Assessment of anal incontinence among patients with fistula in ano, at presentation and after Seton treatment

A dissertation submitted in partial fulfilment of the requirement of MS (Branch – I) General Surgery examination of Tamilnadu Dr. MGR Medical University, Chennai to be held in April 2016

CERTIFICATE

This is to certify that the dissertation entitled “Assessment of anal incontinence among patients with fistula in ano, at presentation and after seton treatment” is a bonafied work by Dr. Komala Abhishek Reddy, submitted in partial fulfilment of requirements for the MS General Surgery (Branch I) examination of the Tamil Nadu Dr. MGR Medical University, Chennai, to be held in April 2016.

Signature

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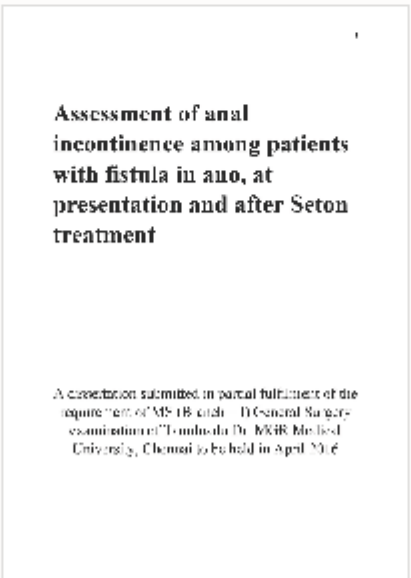

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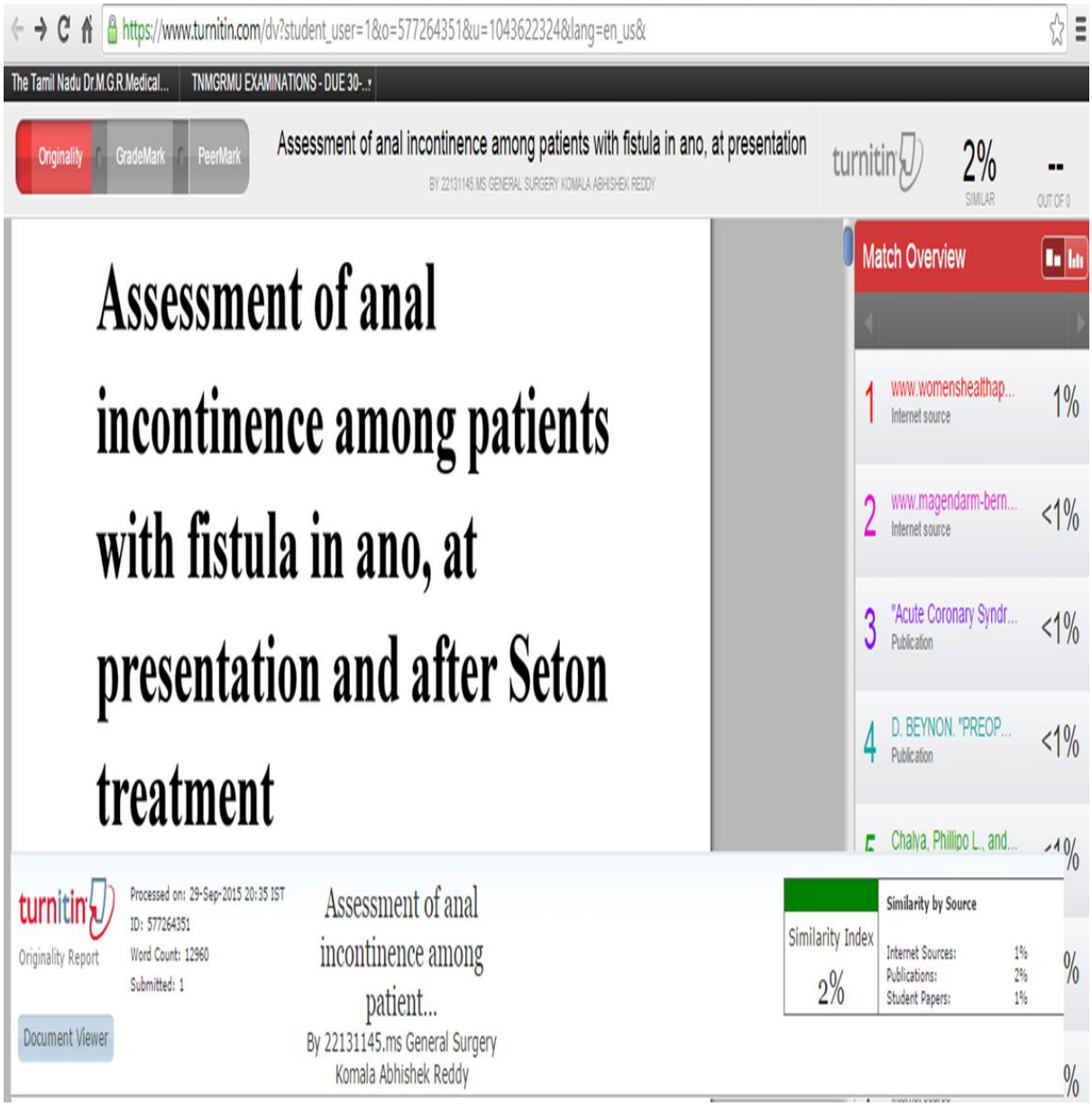


ABSTRACT

Title of the abstract: Assessment of anal incontinence among patients with fistula in ano, at presentation and after seton treatment

Objectives:

1- To assess prevalence of baseline anal incontinence among new patients presenting with fistula in ano.

2- To determine the incidence of new onset anal incontinence following draining seton surgery for fistula in ano

Methods: A prospective observational study with a sample size of 196 patients who presented with fistula in the department of General Surgery II (Colorectal surgery) during the study period. All the patients had incontinence assessment by Kamm's scoring and Wexner's scoring system at presentation in outpatient clinic. They also had anal manometry assessment. The set of patients who had a draining seton surgery done, underwent similar assessment 3 months later to assess continence.

Results:

1 - As per Kamm's scoring system 26.2% patients and according to Wexner's scoring system 23.5% patients had some form of incontinence at presentation itself.

2 – There was no statistically significant post operative new onset of incontinence following draining seton surgery.

Contents

1. Introduction

Fistula in ano is a tubular tract connecting two epithelial surfaces, connecting mucosa of anal canal to the perianal skin. It is lined by granulation tissue. It can present as a single fistulous tract or as multiple tracts. The actual burden of the disease is unknown because it gets underdiagnosed, misdiagnosed, under reported, treatment is mostly tried by traditional methods. The risk of an anal abscess to lead to fistula in ano ranges from 26% - 38%. Other fistulas caused by subacute infection and suppuration of cryptoglandular glands of anal canal. (1) Rarer causes of fistula in ano include malignancy, tuberculosis, hidradenitis suppurativa and crohn's disease.

Fistula in ano starts as a cryptoglandular abscess which is a representation of acute phase, which the infective stage. This stage significantly affects the quality of life and caused significant amount of discomfort when it forms a big abscess. The correct treatment at this stage itself becomes challenging. Surgery is the treatment of choice to control local sepsis. Goal of therapy at this point is control of local infection, removal of fistulous tract with minimal possibility of recurrence, and preservation of anal sphincters function.

There are normally 8-10 anal crypts like glands at the level of dentate line in the anal canal. These are arranged circumferentially. These lead to intersphincteric plane and intramuscular spaces. Thus organism spread can be rapid in this plane. It drains to perianal skin surface with a tubular fistulous tract which is lined by epithelial membrane / granulation tissue. Following surgical or spontaneous drainage if granular

tissue lining remains, it causes recurrence of symptoms. Various treatment options available there is no ideal surgery / therapy for fistula in ano.

The dreadful complication of surgical intervention includes anal sphincter injury, which can result into incontinence or sometimes anal stenosis. The high rate of recurrence also limits the surgical options.

In this study we will assess if fistula in ano itself has a potential to cause anal incontinence, due to local inflammatory changes. We did a baseline anal incontinence assessment for all the patients who presented to us during this study period. We also include patients who underwent surgical intervention elsewhere and presented to department of surgery II (Colorectal surgery department) for the first time during their outpatient clinic visit. We took an account of this past surgery to assess if it can affect incontinence profile.

All the patients who had draining seton type of surgery during this study period, they were assessed for their continence profile after 3 months of surgery also.

This study was beneficial to assess the severity and prevalence of faecal incontinence among patients with anal fistula because most of the time it gets under reported or usually missed. Other aspect of the study determined if there was a new incidence of incontinence following draining seton surgery, as that is one of the commonest used seton surgery. In our institution we use infant feeding tube as a draining seton which is passed through the fistulous tract and it is not ligated tightly (tightly ligated tube is generally used for cutting seton purpose). The incontinence will be assessed based on the incontinence profiles Kamm's scoring system and Wexner's

scoring system, these scoring systems assess the burden subjectively. Anal manometry was also done in this disease to assess continence profile, to get an objective result. It reduces subject based bias. An informed consent was obtained prior to enrolling patient in the proposed study.

2.AIMS AND OBJECTIVES

3- To assess prevalence of baseline anal incontinence among new patients presenting with fistula in ano.

4- To determine the incidence of new onset anal incontinence following draining seton surgery for fistula in ano

3.Literature review

History

Surgery of anorectal fistula has evolved with evolution and progression of human race. It started from the time of Susrutha, in Ayurveda there is a description of seton *('Kshara Sutra')* in their treatment. Instruments unearthed of various civilizations showed various instruments which were used for anorectal fistula surgery. Few instruments were found which were used in procedure like seton placement, incision and drainage.

Perianal fistula has been a common problem seen worldwide. The various treatments have also been described from the beginning of time. Egyptian history reveals that almost in 2500 BC both surgical and medical management were tried. Papyrus also mentioned few treatment options available of that time dated back to 1200 BC under chapter “shepherd of the anus”. Sushruta (Father of Indian surgery) described medical management and well-illustrated surgical treatment options for anal fistula management, which includes incision followed by cauterization. (2)

Earliest documentation of Greece dates back to time of Hippocrates, in 400 BC. It was thought to be secondary to a hematoma, which gets infected and suppurated. He also stressed on correct incision for drainage of abscess, due to frequent recurrence. Fistula in ano were categorized into various categories based on depth from skin

surface. Some fistulas were considered as tubular and those were treated with flax gauze imbibed with copper flower dilation, it was filled through ulcerated internal opening. Otherwise standard treatment was ligature of interwoven horse hair was used at that time. Daily pulling and twisting of knot was practiced, followed by copper flowers cauterization. (3)

Meges (20 BC) described that fistula reaches till bones and cartilage, probably he was giving a description of pilonidal sinus. Celsus (25 BC) described excision of superficial plane, he also introduced probe introduction in the fistulous tract and excision of tract, he also advocated placement of small threads at the site of fistulectomy site. Heliodorous and Antyllos in 1st century A.D. introduced placement of probe in the fistulous tract, it used to be pulled out through the anal canal to lay open the fistula. This method became quite popular in Rome. Galen (200 A.D.) introduced chemical cauterization for treatment of fistula. Aetios (550 A.D.) introduced incision after previous ligature and pulling the tract with a folded probe. (4)

Peter Lowe, wrote in 1612 about fistula in ano very well. He also described three methods which could cure the disease.

a) Burning the fistula with a cautery.
b) Cut open the fistula
c) Ligature of fistula in ano

He preferred ligature of fistula in ano as he found it little less dangerous. The procedure was similar to modern seton surgery. He had good results with ligature. He

also advocated that complicated and complex fistula should not be treated with operation as it can cause incontinence. Ambrose Pare described various methods of fistula surgery in his book, Fistula in the fundament during sixteenth century.
Louis XIV "Le Roi Soleil," was operated for fistula in ano, and the surgeon was given a reward of £6,000.(5)

Since then various modifications have been done in the management of fistula in ano. There is no definite answer for the “best” treatment option for fistula in ano despite of various advanced treatment options available.

Clinical history and Examination

Careful history can lead to diagnosis, often they give a history of previous abscess which drains spontaneously or following surgical intervention. Commonest history obtained from fistula in ano patient is as following, arranged in an order of frequency.

- Perianal discharge
- Pain
- Swelling
- Bleeding
- Diarrhoea
- Skin excoriation
- External opening

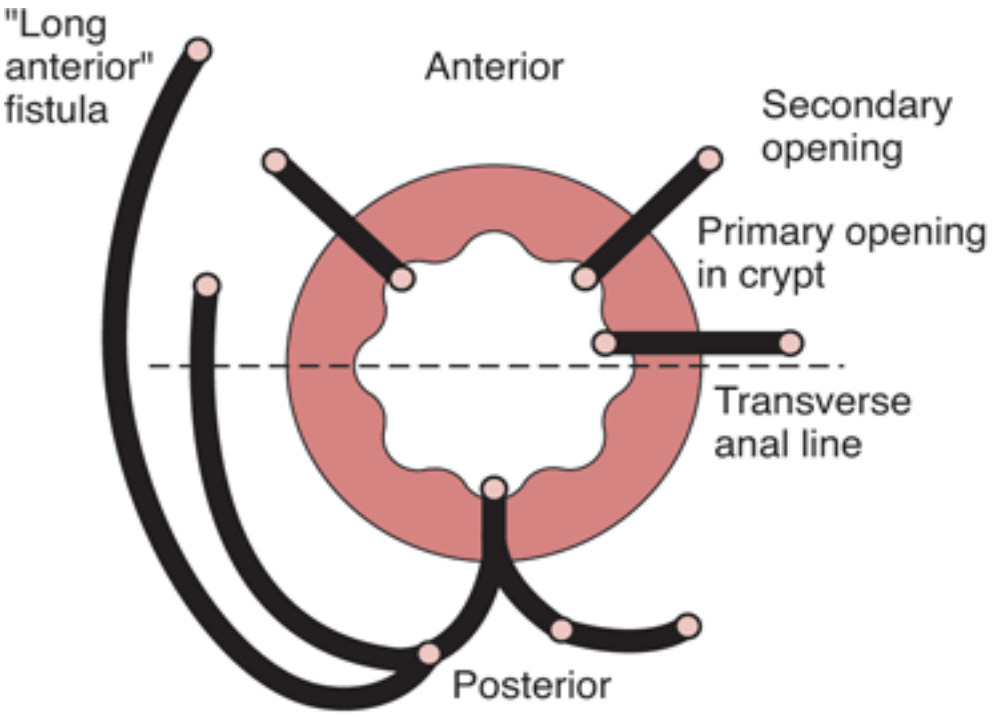
Important relevant history which should be obtained while collecting history, are any symptoms suggestive of following. These are generally associated with complex fistula in ano.

- Inflammatory bowel disease
- Diverticulitis
- Radiation exposure for prostate or rectal cancer
- Tuberculosis
- Steroid therapy
- Immunodeficiency status

During physical examination fistula in normally picked up during inspection of perineum, careful inspection reveals external opening of fistula. Digital rectal examination can help in finding an internal opening, which is generally palpable as mild thick edge sinus, but this is best appreciated by proctoscopy. In cases when internal opening is not visible or palpable, there should be high index of suspicion for complex fistula in ano, because internal opening can be at a higher level than the finger's reach. Both patient, and treating surgeon should be prepared for a complex fistula surgery.

Regarding fistulous tract path, according to Goodsall's rule 'if the external opening is anterior to the transverse anal line and within 3 cm. from the anal verge, the internal opening will be in straight radial line. But, if the external opening is behind the transverse line or more than 3 cm. from the anal verge, the internal opening will be at

the posterior midline of the anal canal'. In such cases the tract will be a tortuous one. But there have been few studies which have proved inadequacy of Goodsall's rule.(6)



Source: Gerard M. Doherty: *CURRENT Diagnosis & Treatment: Surgery, 13th Edition:*

Fig 1: Goodsall rule

Anatomy of the anal sphincter

There various factors that determine continence apart from the sphincters and these include factors like the physical nature of the stool and the nervous system integrity. The physical integrity of the anal sphincter is the most important factor.

The anal sphincters is made up of two components. There is an external anal sphincter and an internal anal sphincter. The internal anal sphincter is an extension of the inner

ring of smooth muscle of the rectal muscle wall region. The external sphincters are linked to the muscles of the puborectalis. There are various components of the anal sphincters. These have been illustrated below

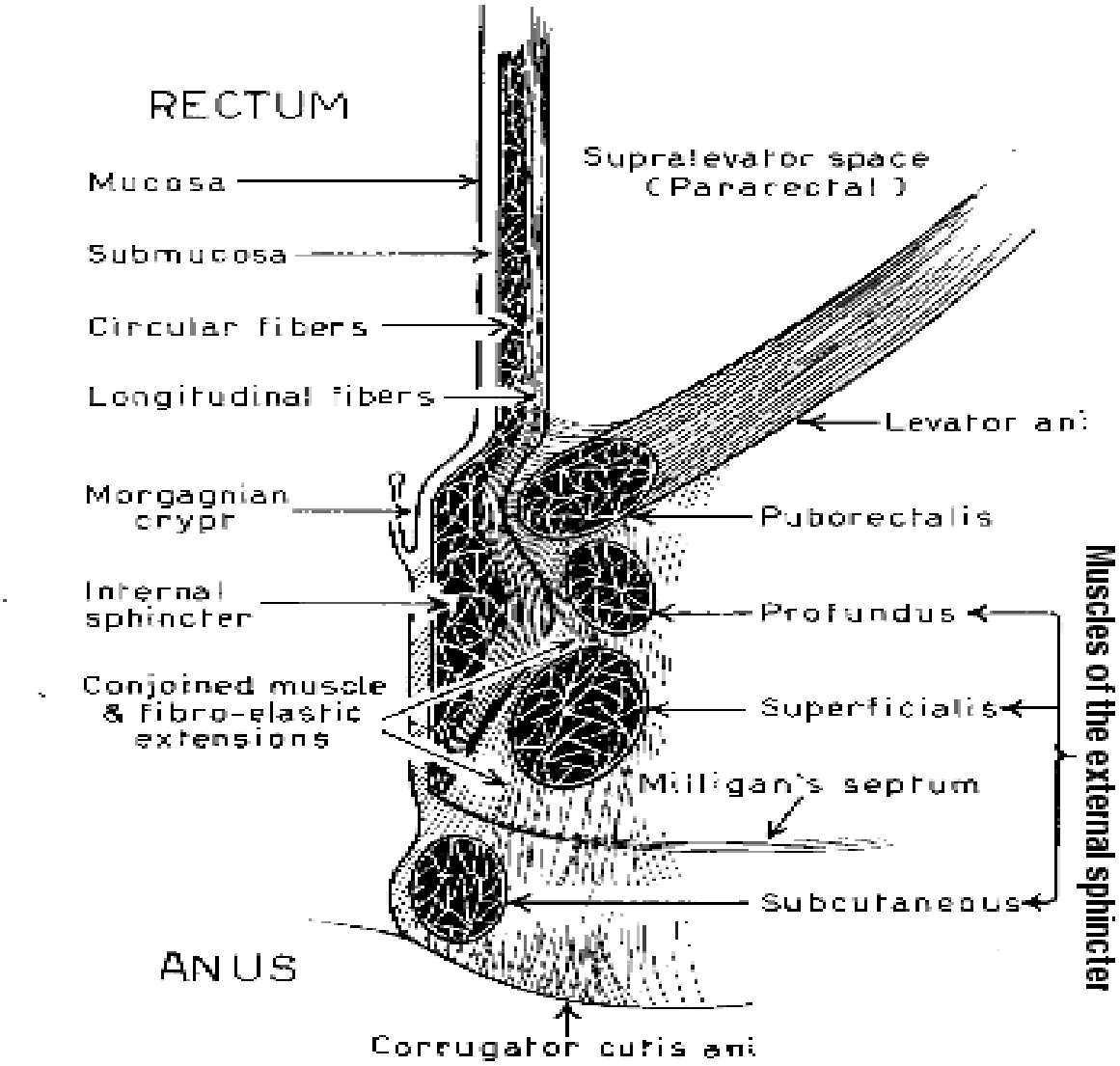


Fig 2: Anatomy of anal canal.

Initial work on ano-rectal sphincter anatomy was done by Goligher J C (Greys anatomy). He demonstrated parts of the sphincter complex by cadaver dissection. He was among the first few to describe the complexion of various muscles that constitute the anal internal and external sphincter.

The internal sphincter is a smooth muscle fibres sphincter. The nerve supply is contributed by the autonomic nerves. This is a sphincter not under voluntary control. The Other muscles of continence control are the external anal sphincter and the Puborectalis muscle. These are voluntary skeletal muscles and are supplied by the sacral nerve and the pudendal nerve. The external sphincter alone does not contribute to the squeeze pressures of the anal canal and it may be contributed by the puborectalis muscle that contributes in the upper anal canal.

Resting anal tone is chiefly provided by the internal anal sphincter (75- 80%) and also by the minimal contribution of external sphincter complex. Resting tone is decided in a resting sphincter continence. Anal continence has many other contributions from the pelvic floor tone that is maintained by the levator muscles, to decreasing anorectal angles that are contributory to maintaining continence.

A fistula-in-ano is an abnormal tract or tubular cavity with an abnormal sinus external opening in the perianal region with a communication with the rectum or anal canal by an identifiable internal opening.(7)

The Recto-anal inhibitory reflex

The Internal anal sphincter is an involuntary muscle that is contracted under basal conditions. The muscle usually relaxes when the rectum distends and hence allows sampling of the anal mucosa of the content of the rectum. This concept forms the genesis of the Recto-anal inhibitory reflex, it is tested by keeping the probe of the anal

manometer at the internal sphincter and allowing a filling of the rectum with a balloon after a baseline sphincter rhythm pattern is measured. A precipitous fall is seen on the graph paper sheet as the sphincter relaxes and then contracts again. This reflex is not seen in Hirschprungs disease; where segments of bowel are chronically tonically contracted where intrinsic innervation has failed to develop.

Classification of fistula

The classification of fistulae is based on its relation with anal sphincters. These have been shown in the drawing. Most of the anorectal fistula fall into the following categories-

Parks Classification(8)

A. Inter-sphincticAnalFistula

B.TransphincticAnalFistula

C.Supra-sphincticAnalFistula

D. Extra-sphincteric Anal Fistula

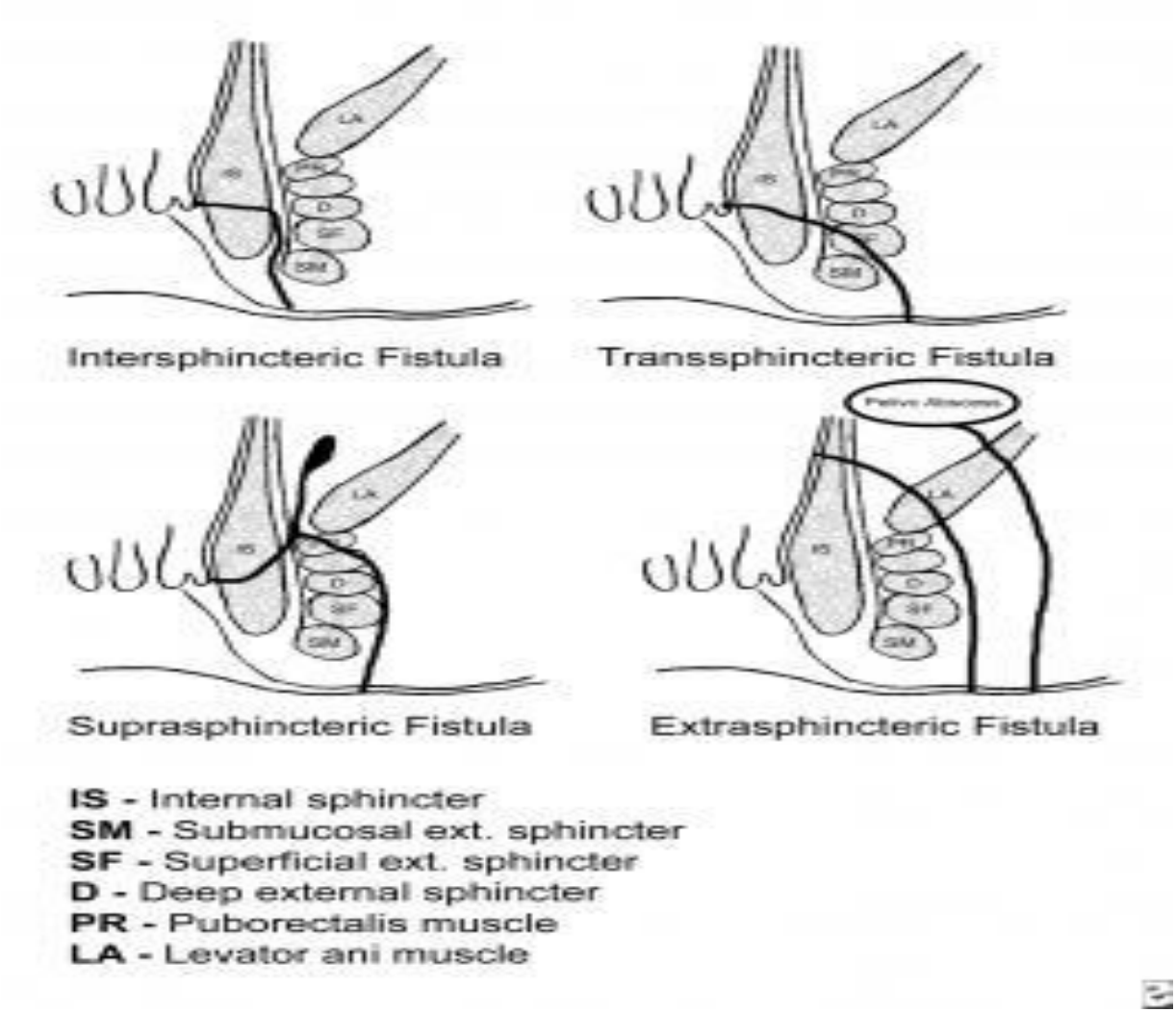


Fig 3 : Park's classification of fistula in ano

'Complex' anal fistula is a more severe and complicated form of anal fistula. They definitely require more complicated therapy. Sometimes, the surgical treatment for these fistula is carried out in stages.

Fortunately, majority of the anal fistula is of the simple type of fistula with minimal muscles fibres involvement. The probability of incontinence increases with increasing amounts of muscle fibres involvement / divided sphincters and the presence of a gutter deformity.

INCONTINENCE

Faecal incontinence is described as an inability to control stool and to expel it at some proper place, at an appropriate time. Its severity can range from mild difficulty in controlling gas to complete loss of control over liquid and formed semisolid stool. It is not clinically lethal, but faecal incontinence is among the one of the most debilitating disease socially, and most of the patients inevitably change their lifestyle according to with their disease. It is a kind of disease which demands a symptom-based approach rather than a traditional disease-based approach

Incontinence is a subjective term and it can mean different for different people. Patient can consider loss of control of stool as incontinence, but for a doctor incontinence of flatus is also an important factor. Incontinence can play a devastating role in the social, personal and sexual life of a person. (9)

Scoring systems for Incontinence

There are many scoring systems were developed to assess evaluation of anal function in reference of faecal continence for anal fissure, Hirschprungs and traumatic incontinence. The references in relation to fistula in ano are few, and there is a scarcity of data from the Indian subcontinent on anal physiology. There are few common incontinence scoring systems that have been studied and proposed –

- The Kamm Score
- The Wexner score
- The American Medical Systems score
- The Pescatori score

These are just few examples of various scoring systems that are used to evaluate incontinence. These scoring systems also look at various aspects of incontinence such as lifestyle modification, leakage of solid stools, liquid stools or flatus, which can deeply affect social life.(10)

These scores give the assessor a set of questions that are reproducible and objective enough to assess the degree of the trouble caused by the problem. There are a multitude of publications that justify the use of one or the other incontinence scoring system. (11)

Incontinence scores were created for standardization of incontinence severity. It reduced subject based bias. Incontinence scores were created not to just asses the severity of the incontinence of stool or flatus, but also to asses its severity and impact on life.

MANOMETRY

Following incontinence scores it was realized that it causes subject based variability. Thus anal manometry becomes an important tool to assess anal functions more appropriately. Since it is an objective test, it is a superior method than other manometry methods. Anal sphincter control is based on two types of muscles fibres.

Smooth muscle fibres which are also known as internal anal sphincter and these are mainly responsible to provide resting anal tone. Another group of muscle fibre which helps in the anal continence function are the skeletal muscles fibres which are also known as external anal sphincters and they are mainly responsible for the voluntary anal function. These are responsible for voluntary control of anal function.

Various anorectal function assessment tools has been studied with various techniques for more than a century. Gowers reported in 1877 first rectoanal inhibitory reflex to assess basic reflex and sensory mechanism of anal canal. (12)

Earlier specially designed catheters were used with balloon in the lower rectum, which were connected to the transducers. It used to transmit the intra-anal pressure to computer and generate graphs to understand the amount of pressure generated by anal canal. It assess the functions of internal and external anal sphincters functions which are responsible for resting and squeeze pressures of anal canal.

Earlier fluid filled balloon catheters were tried to assess the function of anal sphincters. Later air filled balloon catheters were used to assess the anal function, it simplified the technique. It was calibrated and the readings were taken as in case of water filled balloon catheters.

Fig 4: Analog measurement of anal manometry

This is a picture of an air filled balloons complex which were used by Schusters. In this picture number 1 is used for manometers. Number 2 is used for the syringe for insufflation, 3 for the balloon which assess the function of external anal sphincter, 4 assess the function of the internal anal sphincter, 5 the rectal balloon elicits the recto anal inhibitory reflex.

Following enhancement of electronic era the micro transducers were introduced in this technique to assess the anorectal function. These techniques have significantly reduced the artefacts and further helped us to get more accurate results.

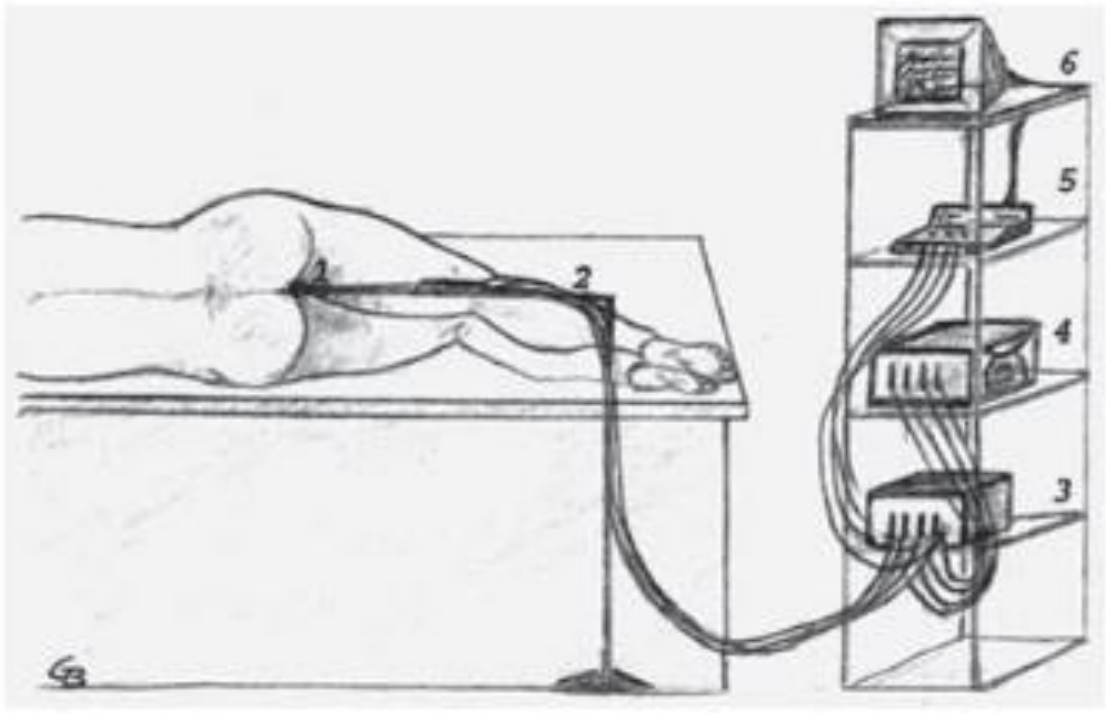


Fig 5: Anal manometry with electro transducer

These instruments were costly, and they were able to serve the purpose most efficiently. It was easy to follow up the patients with accurate change in function of anal sphincters function. Water and air filled balloons were slowly replaced by plastic/metal solid transducer probes. It made the whole technique less cumbersome. (13)

These transducers and outputs recorded on screens, heat sensitive paper or computer screens. The new generation manometers are multi – vector and are able to record pressures at the entire length of the anal canal simultaneously.

Data can be available for various length of the anal canal, regarding resting and squeeze pressures. The internal sphincter and the external sphincter function can be assessed as the voluntary squeeze and recto-anal inhibitory reflex are recorded. The

anal manometer is an important adjunct in the diagnosis of Hirschprungs disease, characterized by an absent RAIR (Recto-anal inhibitory reflex).

Imaging Studies

Radiologic studies are not done regularly because it is easy to identify anatomy of most of the fistulas intraoperative period. But these can be a useful tool to identify a complex fistulous tract and or in a case of recurrent fistula in ano. In case of complicated fistulas sometimes secondary tracts are missed, thus it helps in identification and preoperative planning for fistula treatment. (14)

Fistulography

This is the method in which injection of contrast via the internal opening, after that anteroposterior, lateral, and oblique radiographic images are taken for anatomical delineation of fistula. Fistulography generally doesn't causes much of discomfort and well tolerated. Its specificity ranges from 16-48%.(15)

Due to this limitation, it is generally reserved for cases in which there is a suspicion of a fistulous connection between the rectum and adjacent organs, viz bladder, where it may help to draw a surgical plan prior to examination under anaesthesia.

End anal/endorectal ultrasonography

This involves passage of a 7-10MHz transducer introduced in anal canal to define muscular anatomy and to differentiate intersphincteric from transsphincteric lesions.

Investigations have revealed that the addition of hydrogen peroxide infusion via the external opening can help to outline the fistulous tract course. It is quite useful to help delineate missed internal openings.

These studies are reported to be superior to physical examination alone, in cases which internal opening is difficult to identify, this is a beneficial test. (16)

MRI

Magnetic resonance imaging (MRI) scans show almost 80-90% concordance with operative findings when a primary tract course and secondary extensions are seen. MRI is the study of choice for complex fistulas and recurrent fistulas. It has reduced recurrence rates by providing important information on otherwise unknown extensions. (17)

CT scan

A computed tomography (CT) scan is helpful in the setting of perirectal inflammatory disease than for the cases of small fistulas because it is better for delineating fluid pockets which need drainage in future. CT scanning requires use of oral and rectal contrast. Muscular anatomy is not well defined by CT scan.

Barium enema/small bowel series

These studies are performed if inflammatory bowel disease is a suspicion in cases of multiple fistulas.

Diagnostic Procedures

Proctosigmoidoscopy/colonoscopy

Rigid sigmoidoscopy can be done at the initial evaluation to rule out any associated disease process in the rectum. Further colonic evaluation can be performed if inflammatory/malignancy is suspected.

Examination under anaesthesia

An examination under anaesthesia is the ideal diagnostic tool which involves examination of the perineum, digital rectal examination, and proctoscopy. This is essential to be done before any surgical intervention. It delineates the course of fistulous tract and helps to decide surgical treatment. In case of difficulty in identifying fistulous tract under anaesthesia following schemes can be tried. Several techniques have been described to help locate the course of the fistula and, more importantly, identify the internal opening. They include the following:

- Injecting hydrogen peroxide, milk, or dilute methylene blue into the external opening, which helps in identification of internal opening.
- Traction measures (pulling or pushing) on the external opening also causes a dimpling or protrusion of the involved crypt

- Insertion of a blunt-tipped probe through the external opening helps to outline the direction of the tract (extreme care should be taken not to use excessive force and create false passages)

Treatment indications and contraindications

Indications

Therapeutic intervention is required for all symptomatic patients. Symptoms generally are suggestive of recurrent episodes of anorectal sepsis. An abscess easily develops easily in cases when external opening seals off.

In cases of inflammatory bowel disease related fistulas medical management of the disease should also be planned along with surgical intervention. (18)

Contraindications

If patients' fistula was found incidentally during routine examination, and if patient is symptoms free, no therapy is required. Surgery for fistula-in-ano is not preferred in the setting of an anorectal abscess, where target of therapy is just drainage of abscess and control of local sepsis. But in cases of obvious fistulous tract, fistula surgery can be performed.

Treatment options

Surgery related to fistula in ano may be easy, but the ideal surgical plan of utmost importance. There is a tight balance between recurrence and impaired continence. The most common surgical options available are -

a) ***To lay open the fistulous tract (Fistulotomy)***. This alone is sufficient for most of the simple fistulas. It contributes for 85-95% of primary fistulas surgeries (i.e., surgery for submucosal, intersphincteric, low transsphincteric).

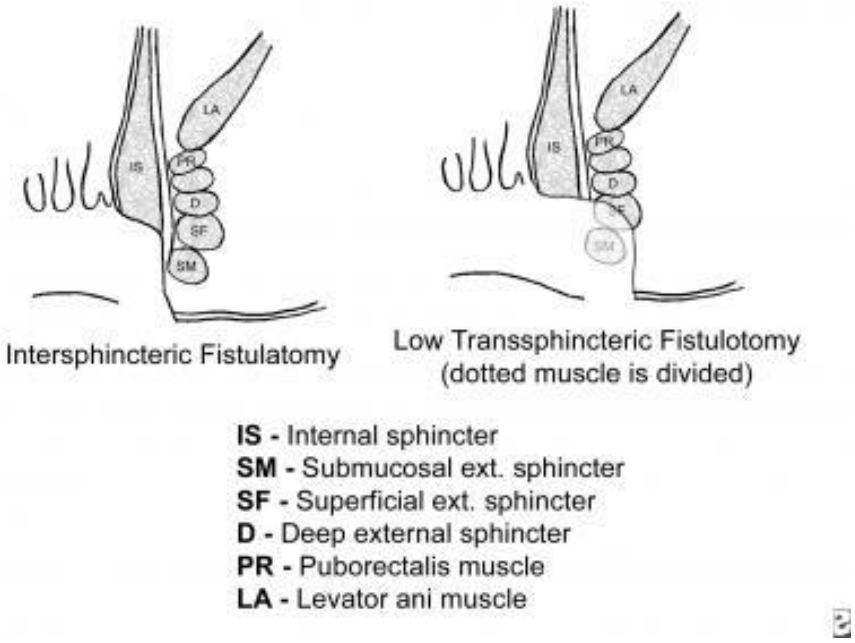


Fig 6: Illustration of lay open fistula surgery for fistula in ano

A blunt tip probe is passed into the fistulous tract through the external and internal openings. The overlying skin, subcutaneous tissue, and internal sphincter muscles fibres are divided with a knife or electrocautery, it leads to opening of the entire fibrous tract. Curettage should be is done to remove granulation tissue from the tract base.

Opening the wound out on the perianal skin surface for 1-2cm with local excision of skin promotes internal healing before external closure. Some support marsupialization of the edges to improve internal healing. Histopathological examination can be done for tissue to find the aetiology of the disease. Fistulectomy - The fistulous tract is totally excised up to the anal sphincter muscle complex region, leaving the wound for secondary healing. Complete fistulectomy gives a larger wounds that take longer time to heal and offers no additional recurrence advantage over fistulotomy.(19)

b) ***To place a seton*** through the tract to slowly separate the tissue with slow simultaneous healing, seton acts as a drain control sepsis.

A seton placement is preferred for the following cases and it can be combined with partial fistulotomy,

- Complex fistulas (viz, high transsphincteric, suprasphincteric, extrasphincteric) or multiple fistulas
- Recurrent fistulas after previous fistulotomy
- Anterior fistulas in female patients
- Poor preoperative sphincter pressures
- Crohn disease or in cases where patient is immunosuppressed

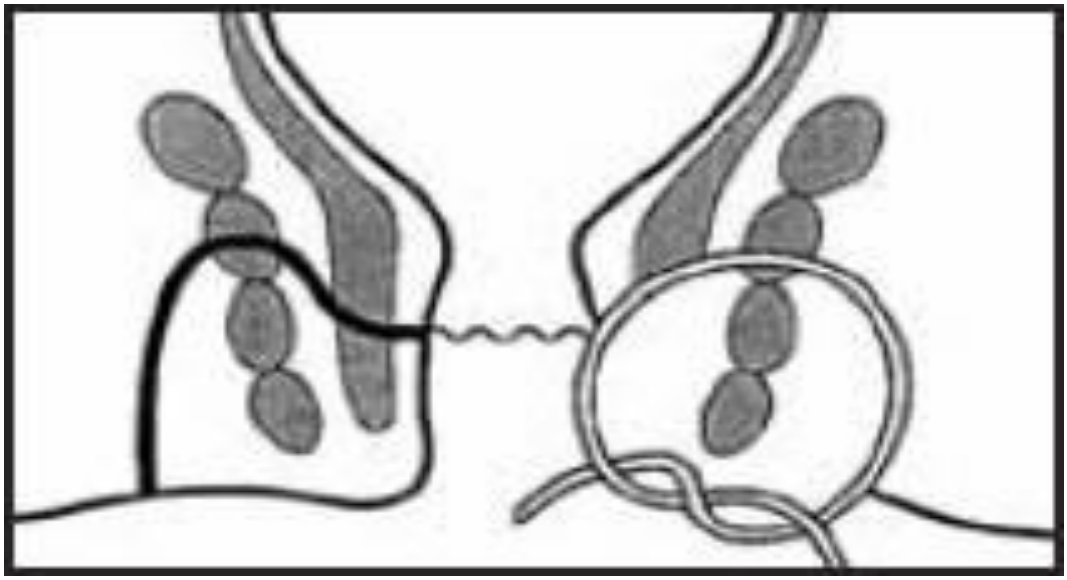


Fig 7: Fistula in ano with seton in situ

The seton helps in visual identification of involvement of muscle fibres involved in the fistula formation. Its main purposes is drainage of the local sepsis and promotion of fibrosis which leads to healing, it also assists slow and steady cutting of fistula. Setons can be made from large silk suture, infant feeding tube, silastic vessel markers, or rubber bands that are threaded through the fistula tract. Two types of seton surgeries have been described classically –

Single-stage seton (cutting)

Pass the seton through the fistulous tract after opening the skin, subcutaneous tissue, internal sphincter muscle, subcutaneous external sphincter muscle. The seton is tightened and secured with a separate silk ties.

With time, it gradually cuts through the sphincter muscles and fibrosis happens of the proximal part, it essentially exteriorizes the tract. The seton is tightened on subsequent

outpatient clinic visits and is pulled through over 6-8 weeks. A cutting seton can also be tried without associated fistulotomy. The success rates for this method ranges from 82-100%; however, long-term incontinence rates can exceed 30% and there is no additional benefit in recurrence rate. (20)

Two-stage seton (draining/fibrosing)

In this method we pass the seton through fistulous tract like cutting seton only. But unlike the cutting seton, the seton is left loose to drain the cause of local sepsis intersphincteric space and it promotes fibrosis in the deep sphincter muscle region. Once the superficial wound is healed fully (usually 2-3 months later), the seton-bound sphincter muscle is divided. Though sometimes healing process can be slow and it can take more than two stages also.

The details of this procedure will be explained in detail with benefits and risks associated with this study, as this is the main procedure used in this study.

c) To remove the primary source fistula (fistulectomy) and to repair the defect with muscle flap

Mucosal advancement flap is normally done for patients with chronic high fistula but indications are same for disease process as seton use. Advantages include a 1-stage procedure with no additional sphincter injury. A disadvantage has been poor success rate in patients with Crohn disease or acute infection.

The procedure involves total fistulectomy, with removal of both primary and secondary tracts and excision of the internal opening also.

A rectal mucomuscular flap generally with a wide proximal base (twice the apex width) is raised. The internal muscle defect should be closed with an absorbable suture, and the flap is sewn down over internal opening so that its suture line does not overlap the muscular repair.

d) ***Other treatment options include fibrin glue, fibrin plugs*** these being non-invasive tend to give less risk of incontinence, but there has been high recurrence rate. (21)(22)

e) ***Ligation of the intersphincteric fistula tract (LIFT)*** which is a sphincter-sparing procedure for complex transsphincteric fistulas was described in 2007. Access is through the intersphincteric plane with the goal of a secure closure of the internal opening and removal of the infected cryptoglandular tissue. A meticulous dissection done through the intersphincteric plane is needed in this procedure. The intersphincteric incision is loosely reapproximated by an absorbable suture. Curettage wound is left opened for regular dressings. The probability of recurrence after 19 months was 8%, there was no difference in incontinence scores pre and procedure. (23)

f) Newer methods like stem cells are promising but have not proven a significant improvement in the management of fistula in ano yet to be used widely.

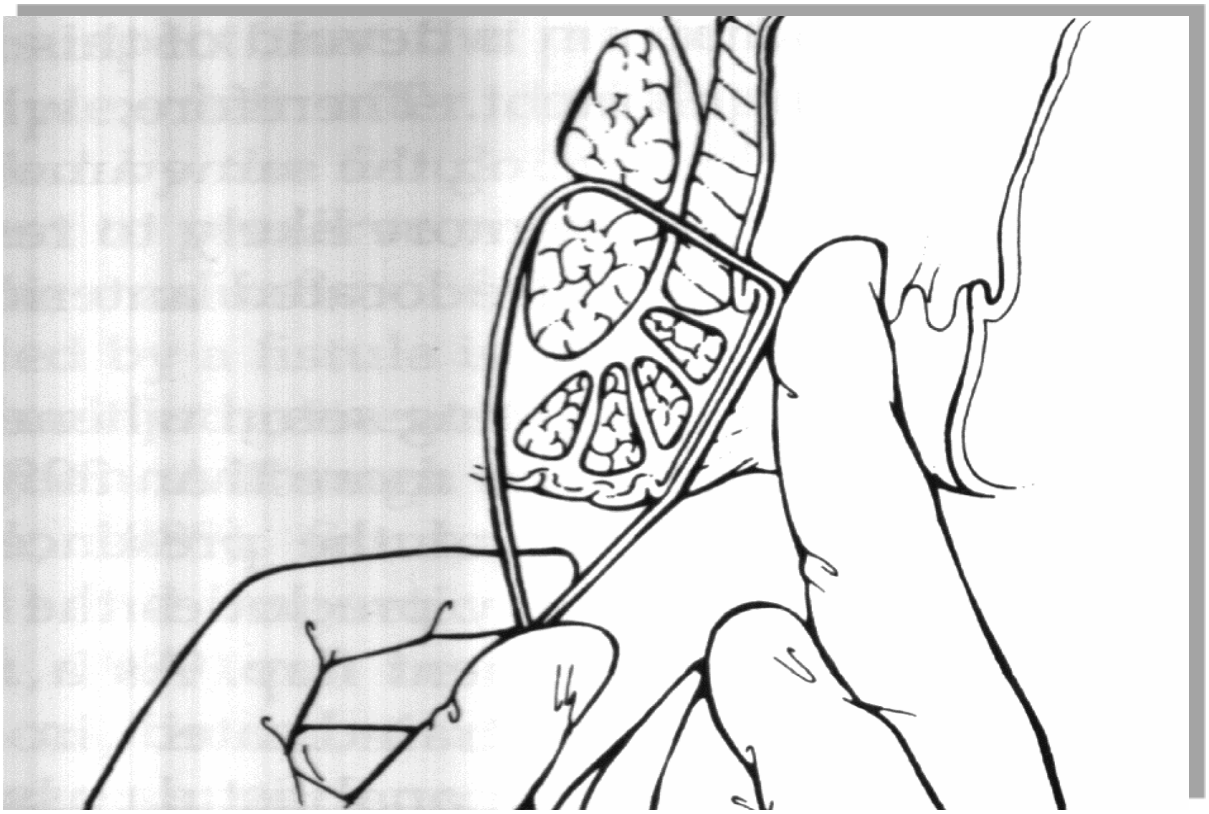
Special note on draining seton surgery

Optimum surgical treatment for anorectal fistulae is one that is associated with low recurrence rates and minimal anorectal incontinence. The main aim of any surgical procedure to cure the disease while maintaining continence. Continence can be regarded as the balance between rectal pressures and the power of the sphincters.

Incontinence following conventional fistula in ano surgery was a dreaded complication. In Indian patients, fistula in ano forms nearly 1.6 per cent of all surgical hospital admissions in hospitals. Many are so relieved by the symptoms of their disease that they do not actively complain of a mild incontinence. A routine history and clinical examination will not reveal the actual number patients.

A review of 624 patients in Minessota Medical School, published in 1996, looked at the factors that are associated with Incontinence and recurrence. The study was a retrospective analysis that looked at fistula type and risk factors. The factors that were associated with recurrence were complexity of the fistula, internal opening identification and type of procedure adopted. The Incontinence predictors, more relevant to the dissertation at hand were reported at 56% of patients that underwent fistula surgery. The duration of follow up was 2.5 months, with the most continence

disorders in the early 2 weeks of surgery. Female sex was a strong predictor of post-operative incontinence. This has been studied in detail and Sultan et al. have demonstrated continence dysfunction after vaginal deliveries. These recommendations had been taken into consideration as the exclusion criteria for the prospective study was prepared. (24)



Another retrospective study, based on a questionnaire based response looked at the various factors for incontinence in fistula surgery. In his study (Van Tes et al), at a centre in the Netherlands – data was analysed for factors to see if continence disorders could be predicted. The various procedures for fistula surgery were compared for their post-operative continence related morbidity. The other factors looked at were the position of the opening, and type of fistula such as position and extensions. The results in this study showed a higher incontinence in patients with

high openings, posterior fistulae and horizontal tracts. The incontinence was measured with a symptom scale (no scoring system used) and was grouped into continent and impaired continence.(25)

One of the earliest studies available is by Park and Stitz done in 1976 (26). It was a retrospective study in which 23 trans-sphincteric and 57 supra-sphincteric fistula in ano were followed for more than 12 months after draining seton surgery. New onset incontinence after surgery was seen in 17% of trans-sphincteric group; in the suprasphincteric group it was around 39%. In 1996 Diseases of colon & rectum published another retrospective study by Lentern and Weinert, (27) which included 79 cases of intersphincteric and low trans sphincteric cases. All cases underwent loose seton surgery. With time 19 setons migrated distally, for rest of the cases fistula track was laid open. Incontinence rate was 1% following the surgery.

In 1993 Pearl et al published another retrospective study in which 89 cases of complex fistula underwent draining seton surgery. They were followed for 23 months. 4% of cases

showed major incontinence. (28) In 1989 Thomson and Ross retrospectively studied 34 cases of high anal fistula, Loose 0-nylon seton used across external anal sphincter after partially doing internal anal sphincterotomy. Patients were followed for 55 months, around 17% developed new onset anal incontinence at the end of study.(29)

Joy and William published another retrospective study with 12 cases in 2002. Loose sialastic catheter was passed across the muscular component of fistula, without any sphincter division. Patients were followed for 19 months. 8% of cases revealed new anal incontinence following surgery.(30) Another recent retrospective study from Seoul, Korea published in 2012 used 3 ‘o’ nylon as loose seton. 53 people were included in the study. After an average follow up of 20 months, this study revealed 3.8% new onset incontinence following surgery.(31) All these studies are limited by small sample size, retrospective nature and have variable results. Thus there is a need to do a prospective study with a large sample size to assess baseline incontinence and incontinence after seton surgery.

4.MATERIALS AND METHODS

This study was is based on the fistula in ano patients who came to department of colorectal surgery. All those who gave consent, underwent two methods of assessments for anal incontinence screening. There was a subjective assessment and also an objective assessment was done.

WEXNER's SCORING SYSTEM

	Frequency				
Type of incontinence	**Never**	**Rarely**	**Sometimes**	**Usually**	**Always**
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears Pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

KAMM's SCORING SYSTEM

	Never	**Rarely**	**Sometimes**	**Weekly**	**Daily**
Incontinence for solid stool	0	1	2	3	4
Incontinence for liquid stool	0	1	2	3	4
Incontinence for gas	0	1	2	3	4
Alteration in life style	0	1	2	3	4

	Yes	No
Need to wear Pad or plug	0	2
Taking constipating medicines	0	2
Lack of ability to defer defecation for 15 minutes	0	4

Two scoring were chosen for faecal incontinence scoring. Wexner scoring system which has been most widely used scoring system to assess faecal incontinence, it is

simple and easy for patients to understand. But it had few limitations like it did not take an account of fecal urgency or need to wear a pad in case of faecal incontinence. There was another scale developed few modifications to improve the assessment of faecal incontinence known Kamm's scoring system. Thus both the scoring systems have been included in this study.

Figure 8: Manometry room with software loaded in computer and anorectal manometry probes and examining table.

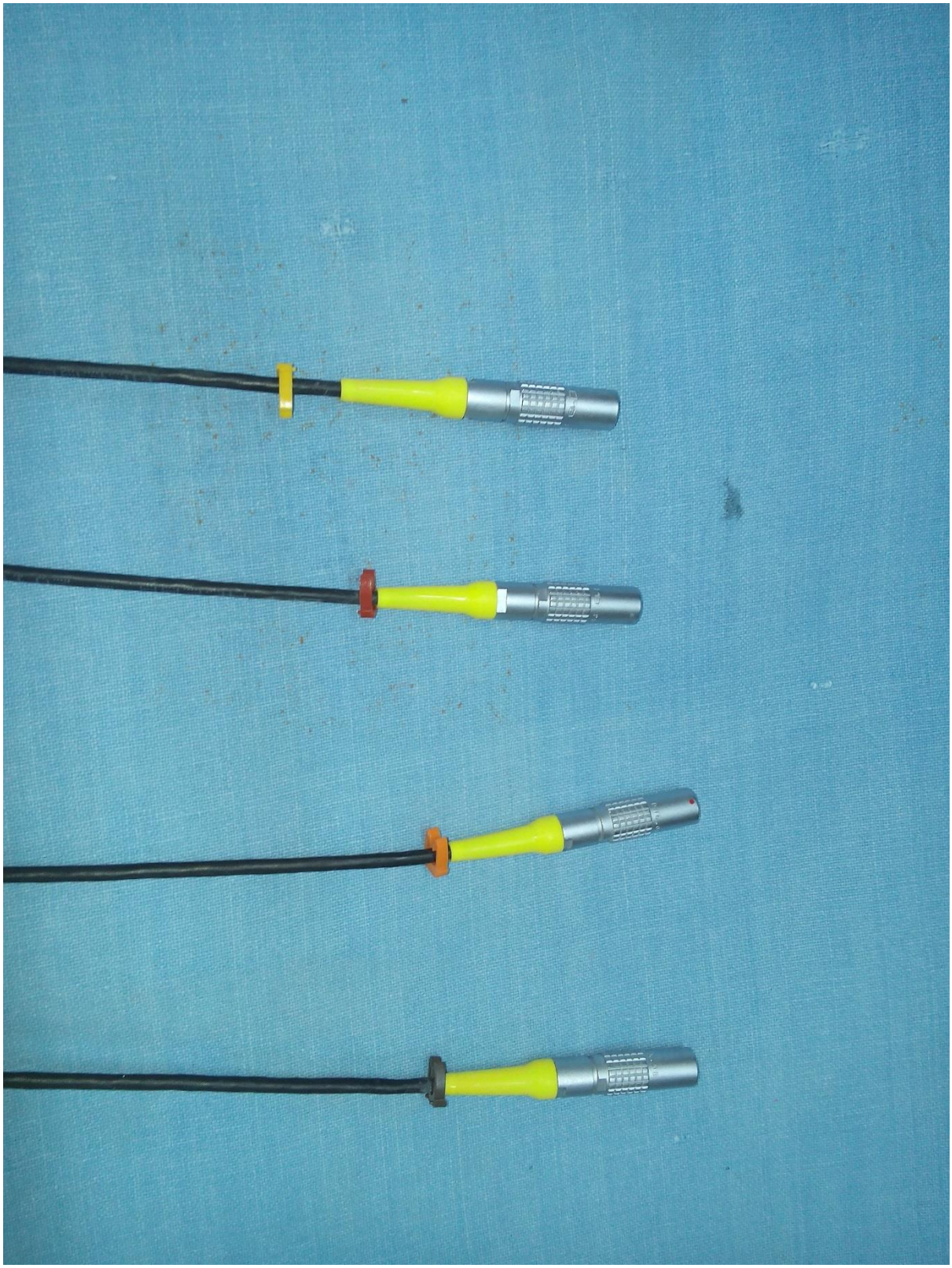


Fig 9: Sensor specific for each level of electro transducer, viz – 3cm, 2cm, 1cm etc.

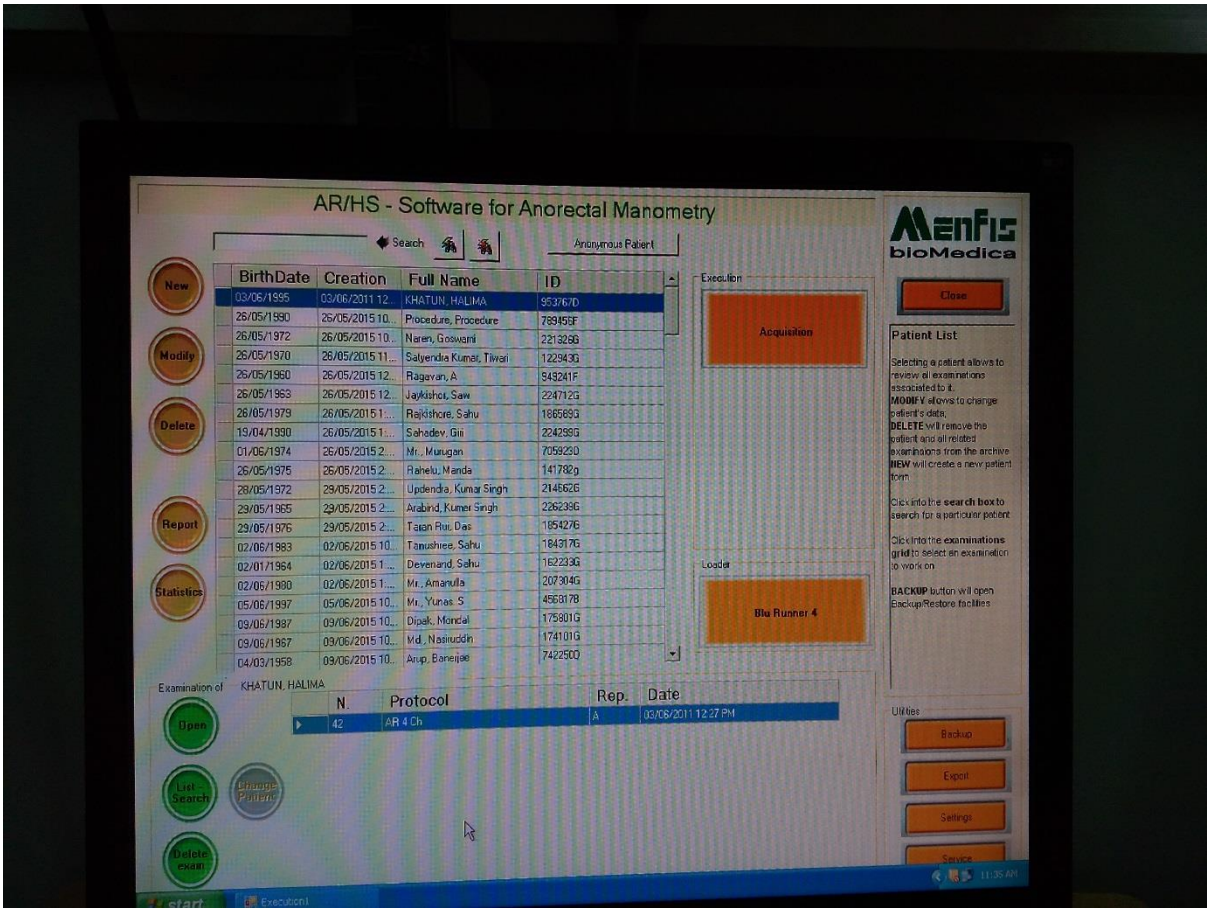


Fig 10: Patients' data on the computer screen

Menfis biomedica with AR/HS software was used to do anorectal manometry, to assess faecal incontinence objectively to increase efficacy of assessment. The assessments were done by the main investigator and manometry technician in colorectal surgery outpatient clinic, in room no 16, on Tuesdays and Fridays during working hours. Patients were examined in the presence of a chaperone. After obtaining their informed consent, they were made lie in left lateral position. Sensor probe was introduced in the anal canal. The length of probe introduced in anal canal was 3 cm from anal verge. An *anal verge* was defined as the opening of anus on the surface of body. The readings from probe was taken after 1 min, this time was provided so that patient can become comfortable with probe in anal canal.

The second minute was taken as resting pressure of anal canal at 3 cm which was measured between 1 – 2 minutes. After that patients were asked to squeeze their anal canal and the reading in the graph was taken as squeeze pressure at 3 cms. After that patients were asked to relax for 30 secs. During this time probe was pulled 1 cm outside at the length of 2 cm from anal verge. The relaxation duration was prolonged sometimes in case of an anxious patient. The reading after 30 seconds at 2 cm from anal verge were taken as resting pressure of anal canal at 2 cm. Following this patients were asked to squeeze their anal canal and pressures were taken as squeeze pressure at 2 cm. Following this patients were asked to relax for another 30 seconds (relaxation time was prolonged in case of anxious patients). Then probe was pulled 1 cm outside the anal verge that means 1 cm from anal verge. The resting tone at this point was taken as resting pressure of anal canal. Then patients were asked to squeeze and before, the reading was taken as squeeze pressure at 1 cm. Then the sensor port was removed.

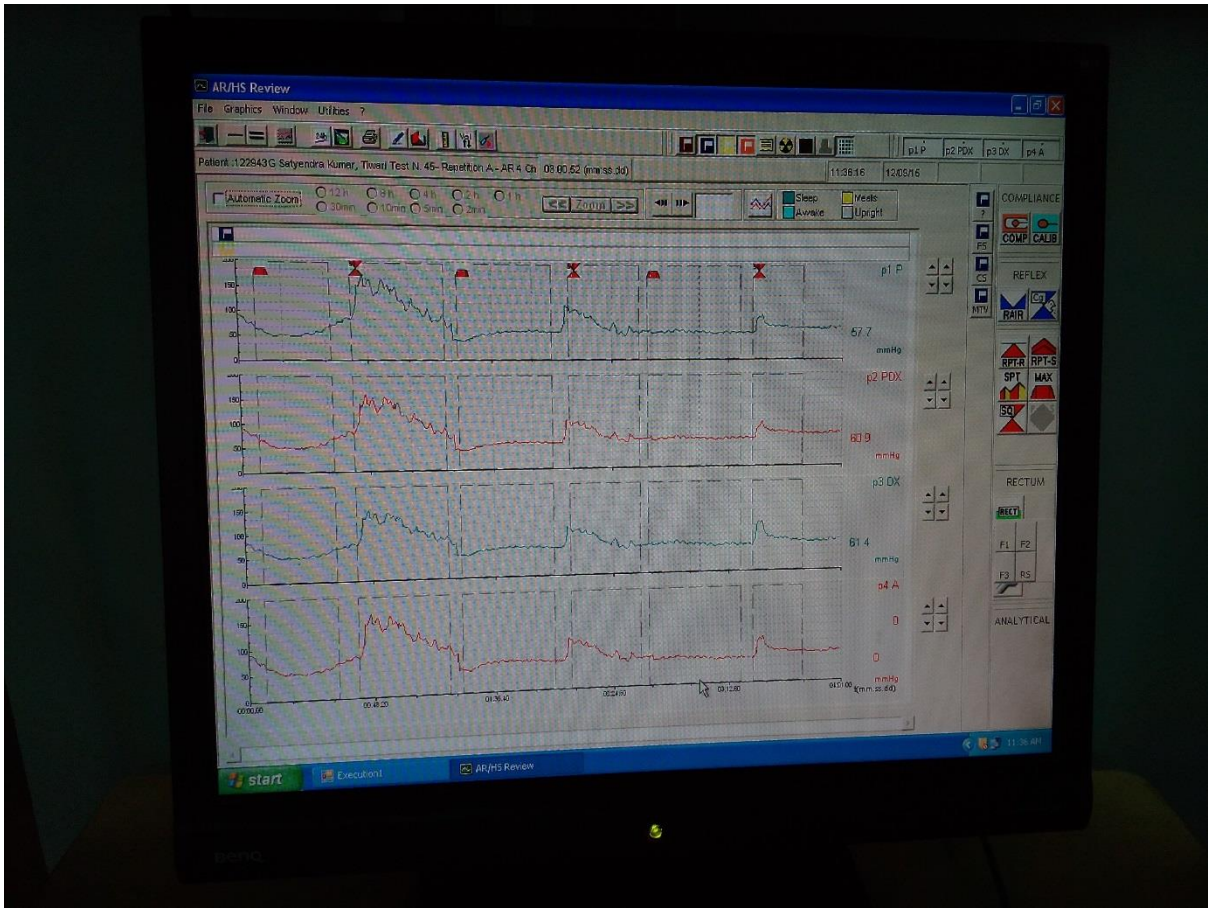


Fig 11: Computer generated graph of anal manometry

Following primary assessment, patient had their routine blood tests viz – haemoglobin, creatinine and blood borne viral screening. Based on the age, comorbidities patient also had electrocardiography and chest x-ray and other essential tests. After obtaining clearance from pre anaesthesia clinic patients' were posted for surgery.

Intraoperative findings were noted down and what type surgery was done was also noted. All patients were taught post operatively about the local hygiene and digitation of the wound with 0.2% lignocaine gel thrice daily before sitz bath. Patients who underwent draining seton surgery were followed up after 3 months. They had

rescreening of anal incontinence with both subjective and objective measurements as done before first surgery.

All the patients were taken for this study, only after they understood the procedure and they got enough opportunities to ask their doubts at any point of time. They were explained the procedure in the language which they could understand, they were provided an information sheet about this study. It was also conveyed to them their involvement is completely voluntary and they can withdraw at any time, without giving any reason, without their medical or legal rights being affected. It was assured to them that their identity will be kept confidential, but their health records will be used for current study and any further research that may be conducted in relation to it. Permission was taken to publish the outcome without revealing the identity.

Inclusion Criteria

All consenting new patients with a diagnosis of fistula in ano who presented to surgery II outpatient clinic for the first time.

For post-operative assessment of incontinence– Patients undergoing draining seton surgery, with cryptoglandular disease

Exclusion criteria

All the patients who did not give a consent to participate in this study.

All the patients who had a seton surgery done within 3 months for fistula in ano.

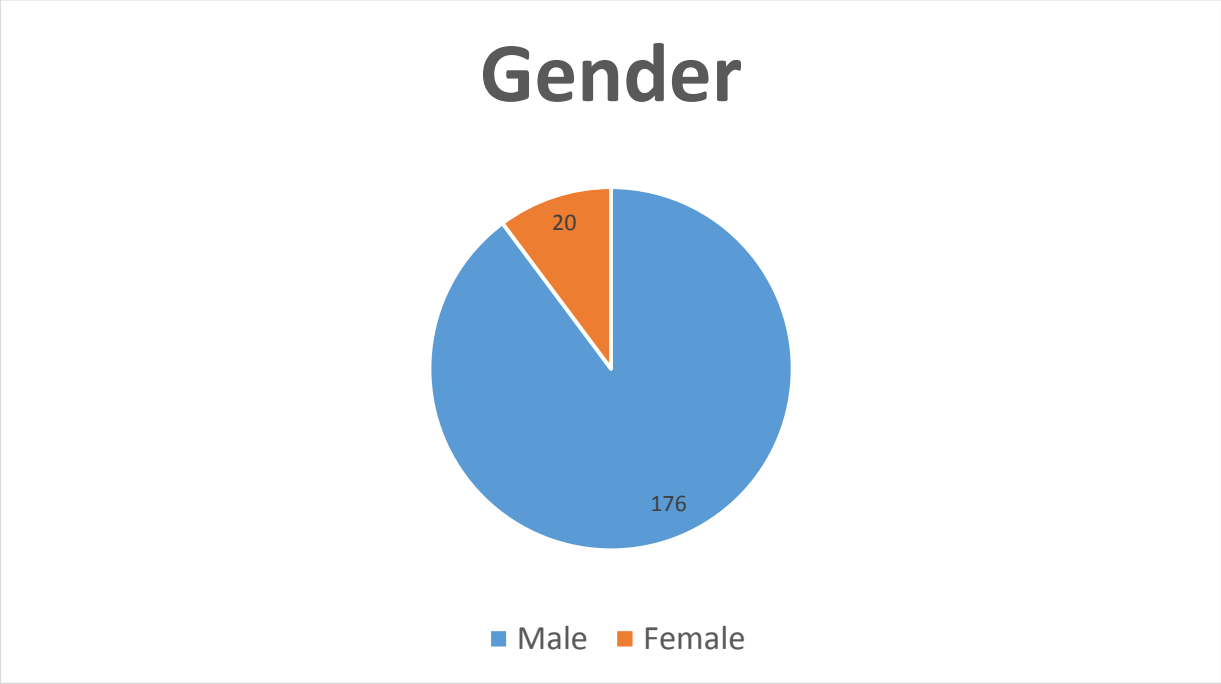
***Variables*:** The following variables were assessed in this study -

- Resting anal pressure
- Squeeze anal pressure
- Wexner and Kamm incontinence scores
- Age
- Gender
- Duration of Fistula
- Etiology of fistula
- Co-morbid illness
- Previous anal operations
- Previous childbirth, obstetrics trauma
- Park’s classification

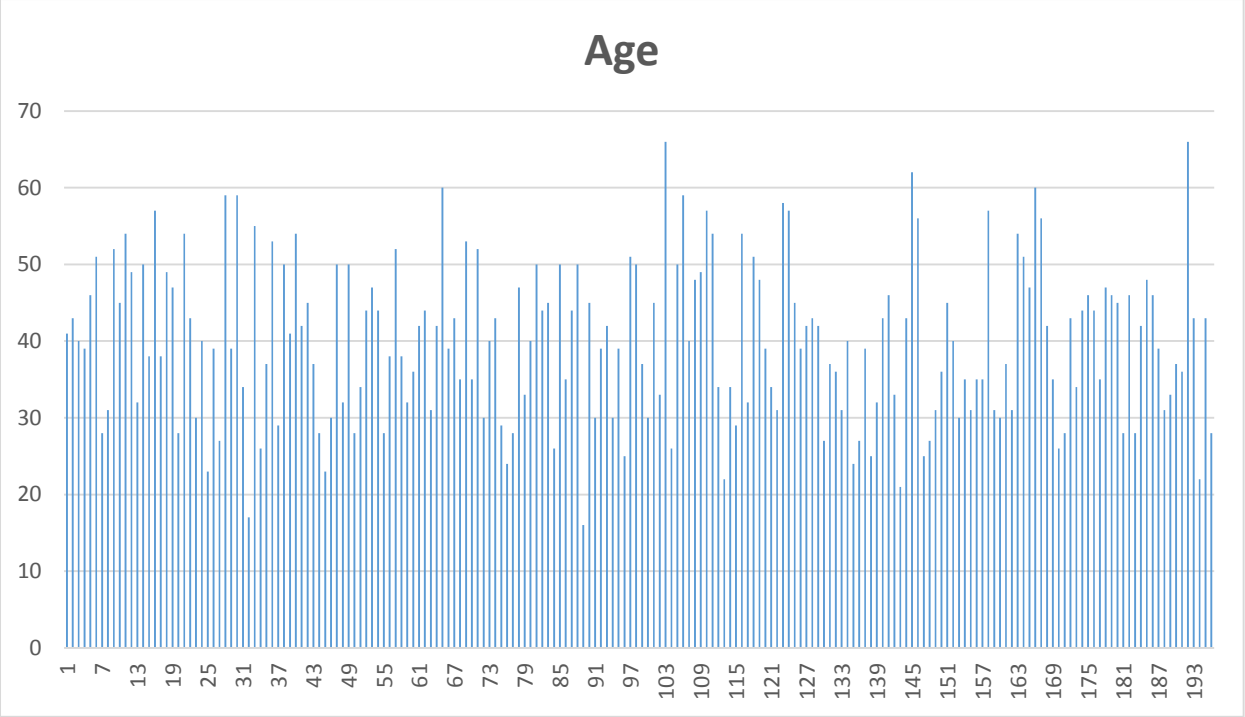
5.Results and Analysis

These are the result of the study which was performed between 08/05/2014 to 02/07/2015. There were 196 patients who gave consent to participate in this study, all of them had a fistula in ano. They were taken for study from surgery II (colorectal surgery) outpatient clinic.

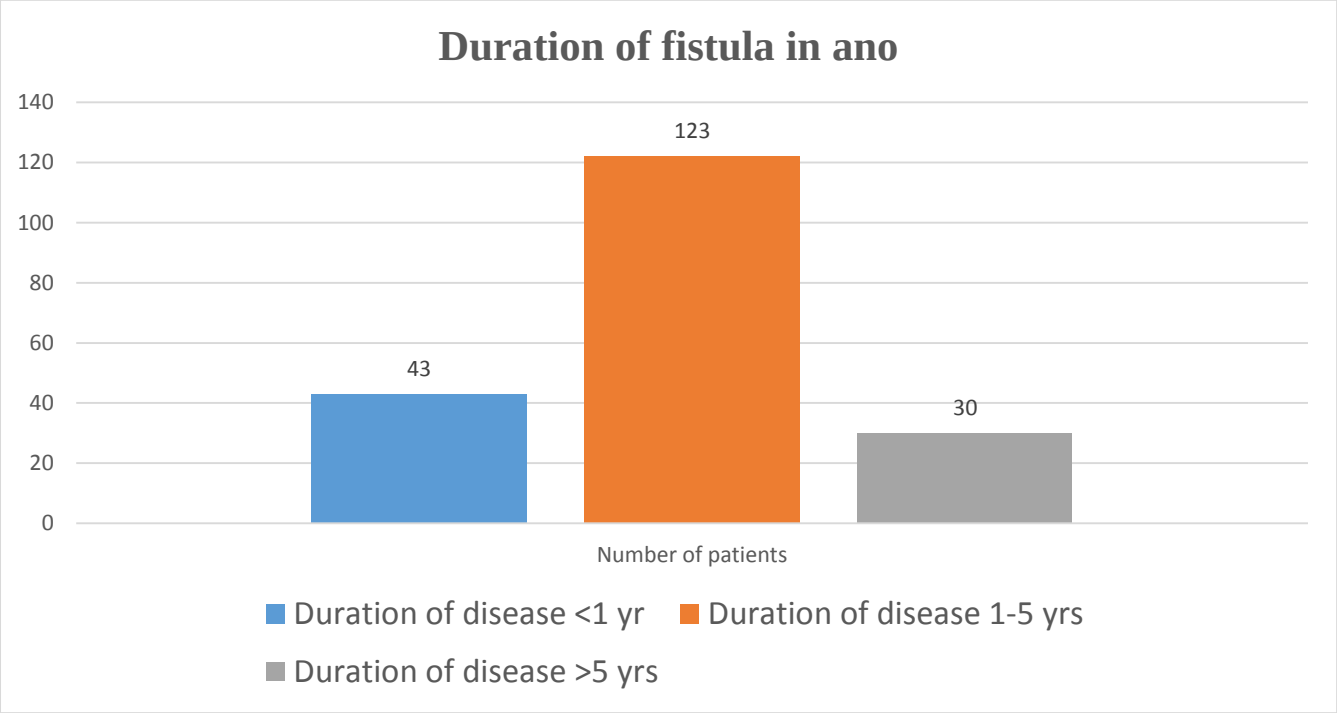
Among 196 patients 176 (89.8%) patients were males and 20 (10.2%) patients were female patients.



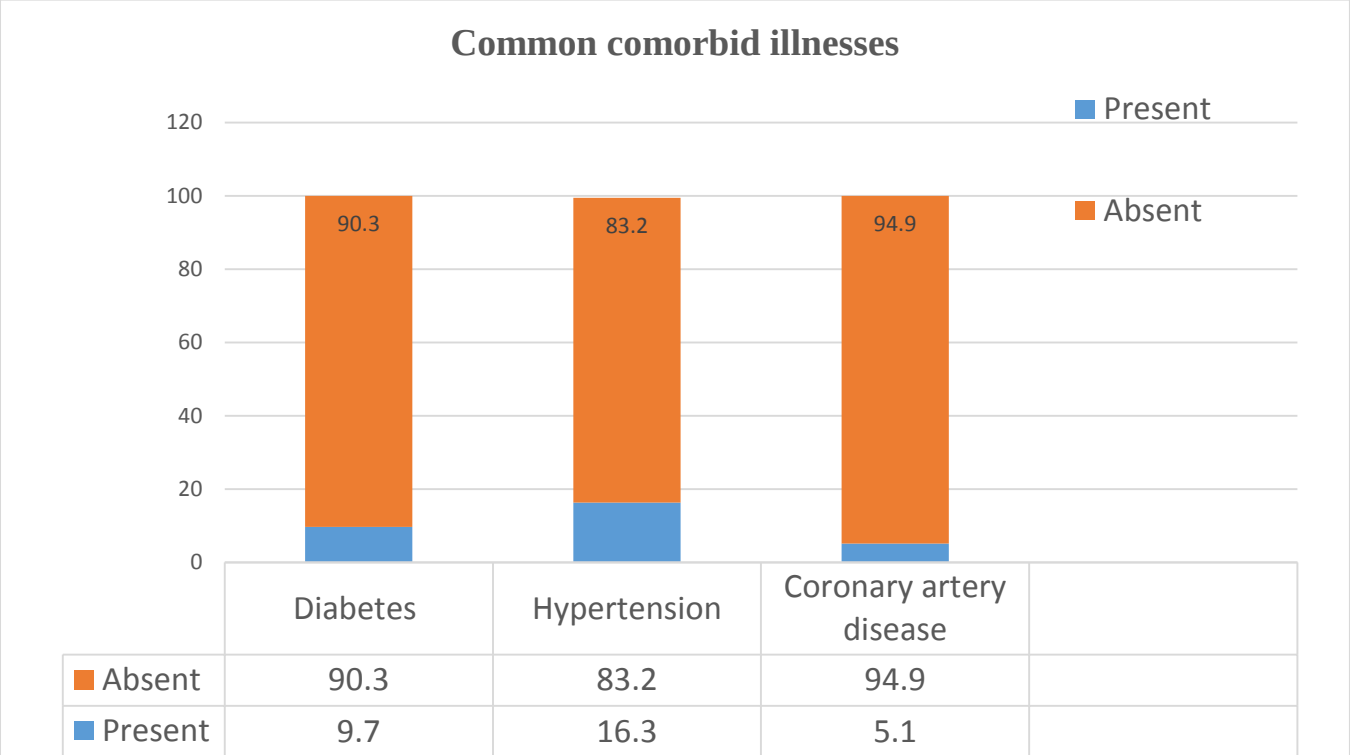
All these patients were asked about their basic demographic details. Among these patients maximum were in the age category of 25 – 50 years.



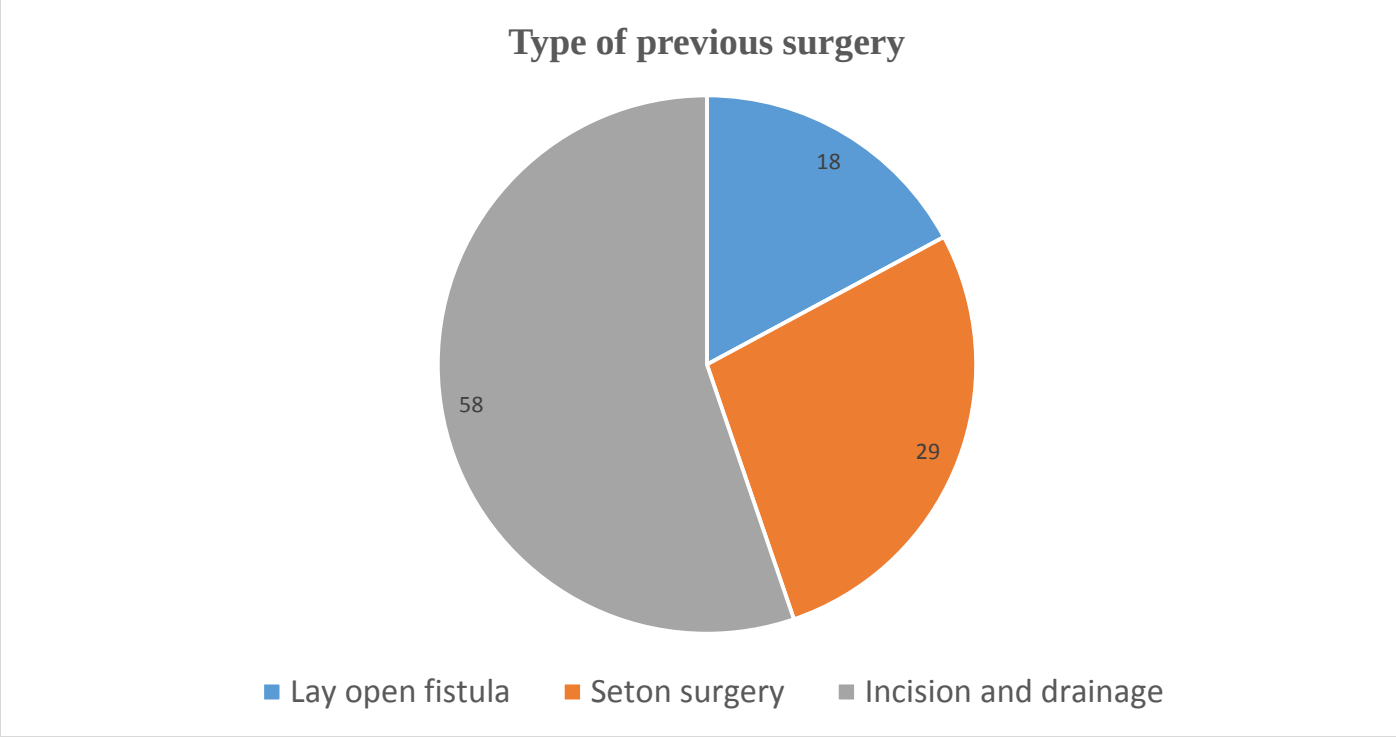
On interviewing about the disease, it was found that 62.6% patient presented with a history of disease duration between 1-5 years, 22.1% patients presented early to seek treatment of their illness and 15.4% patients were suffering with disease for more than 5 years duration.



There was none of the patient who gave history of tuberculosis in the past. Out of 196 patients, 19 (09.7%) patients had diabetes mellitus. 32 (16.3%) had diagnosed hypertension. 10(05.1%) patients gave history of coronary artery disease in the past.



105 (53.6%) patients gave a history of past perianal region surgery, 91(46.4%) patients did not give any past history of surgery. Most of these surgeries were drainage of the perianal abscess (more than 50% patients underwent incision and drainage of perianal abscess).



Among these operated patients 31.1% patient had only one surgery in the past, while rest of them were operated more than once.

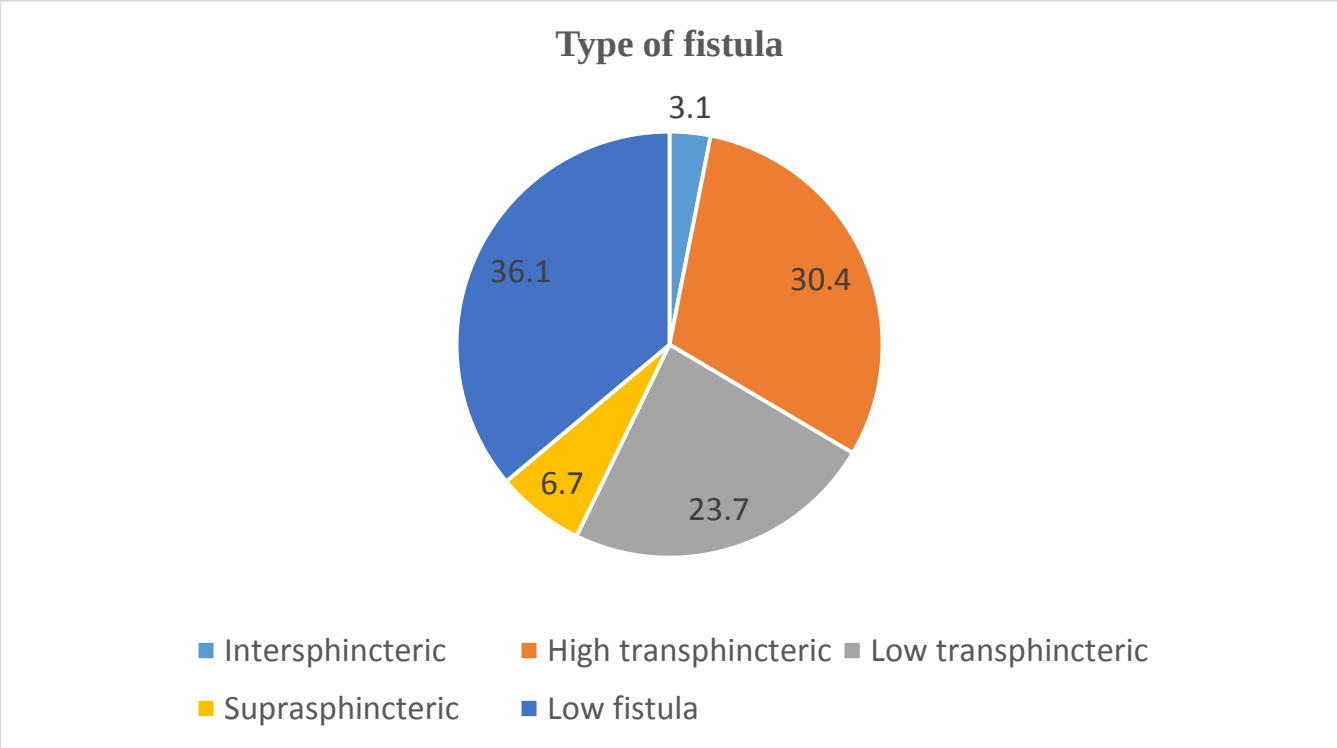
	Number of patient	Percentage
Operated only once	61	58
Operated more than once	44	42
	105	100

The profile of type of fistula for these patients had been described in the following table.

Type of Fistula

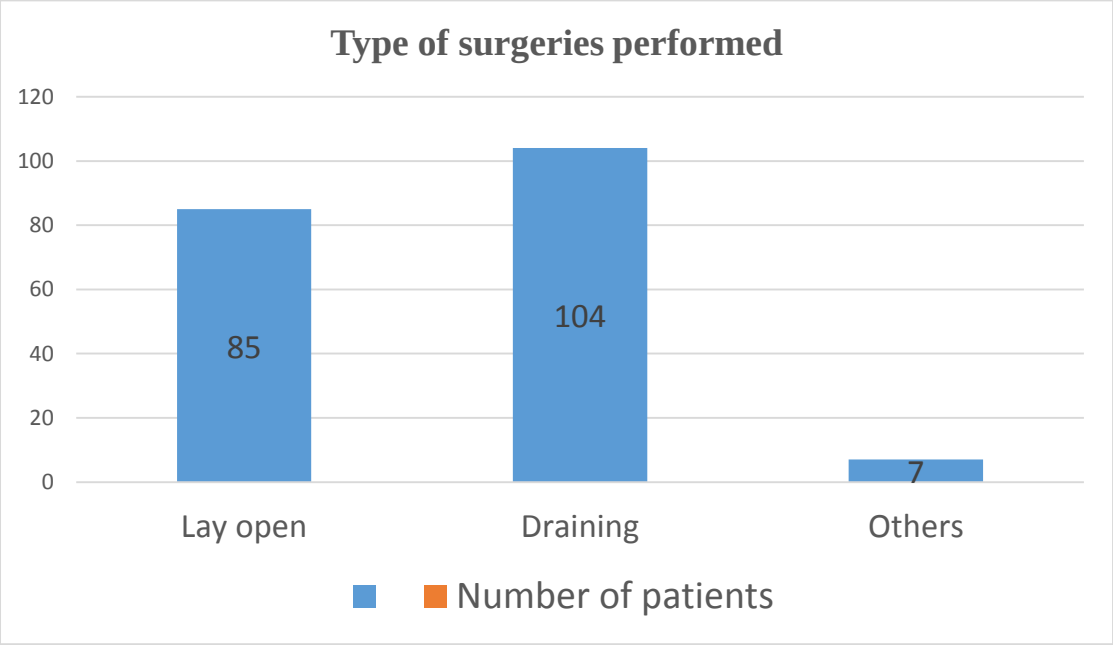
	Number of patients	Frequency
Intersphincteric	6	3.1
High transphincteric	59	28.4
Low transphincteric	46	23.7

Suprasphincteric	13	6.7
Low fistula	72	38.1

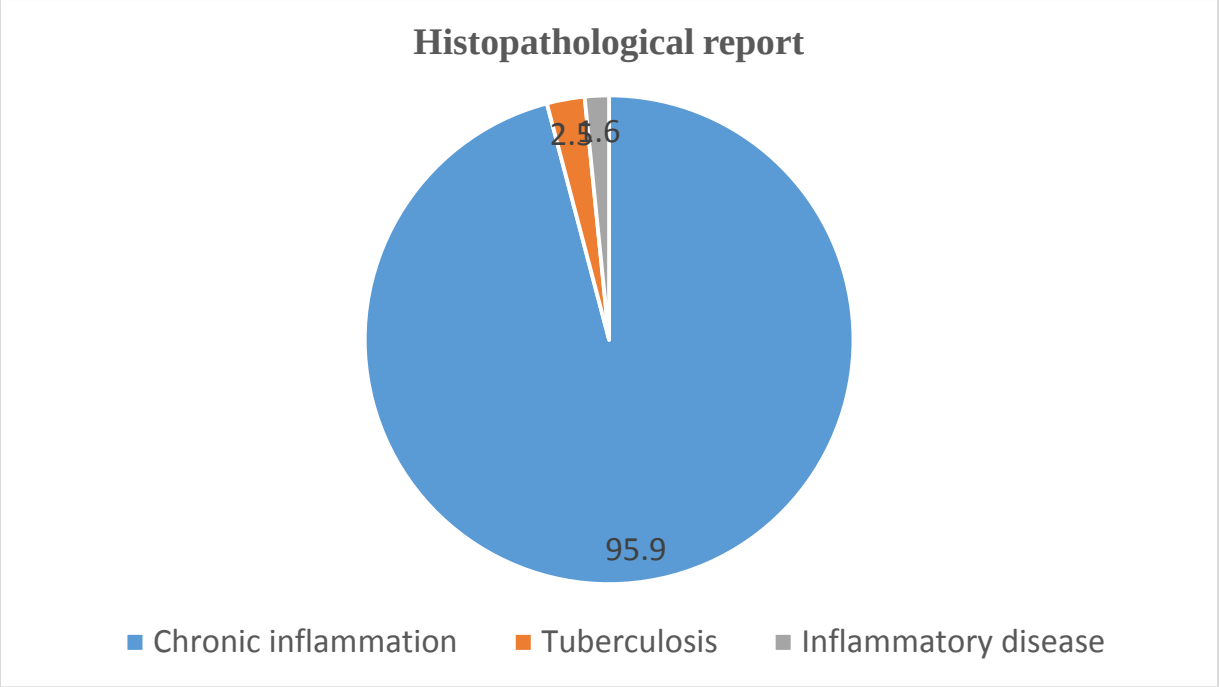


Among these patients 43.4% patients underwent lay opening of fistula which was preferably done for low fistula and sometimes based on the amount of muscle fibres involvement for low transphincteric fistulas also. Low transphincteric fistulas with lesser number of muscles fibres involvement were laid open and no seton insertion was done. This decision was left for surgeon to decide that which fistula requires seton or which fistula needs to be laid open.

53.1% patients had a seton insertion done, following which they were reassessed after 3 months for incontinence studies (both objective and subjective assessment). 3.6% patients had other procedures like mucosal advancement flap, glue, plug insertion etc.



Histopathological examination was done of all fistula in ano. Tissue biopsy was done and based on that 188 patients were found to have chronic inflammatory changes or acute on chronic inflammatory disease process. 5 patients were found to have tuberculosis changes. 3 patients had inflammatory disease changes. It was suggestive of crohn's disease. These patients were given appropriate medical therapy also.



Microbiological examination revealed tuberculosis positivity in 3 cases. Among 5 cases who had tuberculosis confirmed by histopathological examination 2 did not reveal microbiological tests.

The incontinence score assessment done for 196 patients was preoperatively was as mentioned below.

Kamm score pattern preoperatively –

Kamm score	Number of patients	Percentage
0	144	73.8
1-2	25	12.3
3-4	12	6.2
>=5	15	7.7
Total	196	100.0

Wexner's score preoperatively –

Wexner's score	Number of patients	Percentage
0	150	76.5
1-2	27	13.8
3-4	11	5.6
>=5	8	4.1
Total	196	100.0

Resting pressure and squeeze pressures assessed preoperatively

	Number of patients	Mean	Std. Deviation
Manometry resting pressure preoperative	196	66.606	21.8529
Manometry squeeze pressure preoperative	196	124.840	57.5704

Among 196 patients 104 patient underwent draining seton surgery. Among these 104 patients who underwent draining seton surgery, 91 followed up after 3 months. They had both subjective and objective assessment done.

Here we will see the results of this study in stepwise pattern –

a) Factors affecting preoperative Kamm score, Wexner's scoring

b) Difference between pre and post-operative Kamm score, Wexner's scoring

c) Factors affecting resting anal tone pre and post draining seton surgery

d) Factors affecting squeeze pressures pre and post draining seton surgery

a) Factors affecting preoperative Kamm score, Wexner's scoring

Relation of age with incontinence scores preoperatively –

		Pre-operative KAMM Score				p-value
		0	1-2	3-4	>=5	
Gender	Male	59(90.8%)	19(95%)	4(100%)	2(66.6%)	0.385
	Female	6(9.2%)	1(5%)	0	1(33.3%)	

		Pre-operative WEXNER Score				p-value
		0	1-2	3-4	>=5	
Gender	Male	65(90.2%)	12(100%)	5(100%)	2(66.6%)	0.281[c]
	Female	7(9.7%)	0	0	1(33.3%)	

Here is p value is less than 0.5, there can be a significant influence of gender in Kamm score. Relatively males have higher risk of developing incontinence. But this can be influenced by the factor that we did not get enough female cases.

Relationship of duration of disease with incontinence scores –

		KAMM Score				p-value
		0	1-2	3-4	>=5	
Duration of fistula in ano	<1 yr.	11(16.9%)	1(5.2%)	1(25%)	1(33.3%)	0.145
	1-5 yrs.	48(73.8%)	12(63.1%)	3(75%)	1(33.3%)	
	>5 yrs.	6(9.2%)	6(31.5%)	-	1(33.3%)	

		WEXNER Score				p-value
		0	1-2	3-4	>=5	
Duration of fistula in ano	<1 yr.	12(16.6%)	0	1(25%)	1(33.3%)	0.286
	1-5 yrs.	52(72.2%)	8(66.6%)	2(50%)	2(66.6%)	
	>5 yrs.	8(11.1%)	4(33.3%)	1(25%)	0	

The prolonged disease causes significant increase in risk of developing incontinence as p value is less than 0.5, it signifies that longer the disease, there will be more risk of developing incontinence.

Relationship between the comorbid illnesses and incontinence scores

		KAMM Score			
		0	1-2	3-4	>=5
Number of patients	History of diabetes	5	2	0	0
	History of Hypertension	8	5	0	0
	History of coronary artery disease	2	2	0	0

		WEXNER Score			
		0	1-2	3-4	>=5
Number of patients	History of diabetes	5	2	0	0
	History of hypertension	10	3	0	0
	History of coronary artery disease	3	1	0	0

The p value of Kamm score with diabetes, hypertension were 0.811, 0.502, 0.445 and the p value for Wexner's score were 0.618, 0.672 and 0.632. Thus there is no serious correlation was seen between the comorbid illnesses and severity of anal incontinence.

Relationship between previous perianal surgeries and incontinence scores

		KAMM Score				p-value
		0	1-2	3-4	>=5	
Number of peri anal surgery	Never had perianal surgery	22	6	0	2	0.055[c]
	One perianal surgery	29	4	2	1	
	More than one perianal surgery	14	10	2	0	

		WEXNER Score				p-value
		0	1-2	3-4	>=5	
Number of peri anal surgery	Never had perianal surgery	25	3	0	2	0.217
	One perianal surgery	30	3	3	0	
	More than one perianal surgery	17	6	2	1	

There was a significant relationship was noticed between the number of perianal surgeries and risk of developing anal incontinence.

Relationship between type of previous surgery and its association with anal incontinence

		KAMM Score				p-value
		0	1-2	3-4	>=5	
Type of past surgery	Lay open	6	3	0	0	0.806[C]
	Draining	14	5	2	0	
	Incision	24	6	2	1	
	Others	21	6	0	2	

		WEXNER Score				p-value
		0	1-2	3-4	>=5	
Type of past surgery	Lay open	7	2	0	0	
	Draining	16	2	2	1	
	Incision	25	5	3	0	
	Others	24	3	0	2	0.587 [c]

There was no significant increase was noticed with relation to type of previous perianal surgeries performed.

Relationship between type of fistula and Kamm and Wexner's scores

		KAMM Score				p-value
		0	1-2	3-4	>=5	
Types of fistula	Intersphincteric	1	1	0	0	
	High transsphincteric	40	9	1	2	
	Low transsphincteric	16	8	2	0	
	Suprasphincteric	7	2	1	1	
	Low Fistula	1	0	0	0	0.431[C]

		WEXNER Score				p-value
		0	1-2	3-4	>=5	
Types of fistula	Intersphincteric	2	0	0	0	
	High transsphincteric	42	7	1	2	
	Low transphincteric	19	4	3	0	
	Suprasphincteric	8	1	1	1	
	Low fistula	1	0	0	0	0.619 [c]

According to Kamm's score there is minimal correlation was seen in incontinence with incontinence and severity of fistula, but Wexner's scoring did not give a conclusive correlation between these two

Statistical view - p-value assessing the association of risk factor with KAMM score or WEXNER's using chi-square test; also p-value using one-way anova and p-value also obtained using fishers exact test

Relationship between incontinence scores and histopathological examination / microbiological examination

		KAMM Score			
		0	1-2	3-4	>=5
AFB/TB PCR	Positive	2	0	0	0
Biopsy report	Chronic inflammation	63	19	4	3
	Others	2	1	0	0

		WEXNER Score			
		0	1-2	3-4	>=5
AFB/TB PCR	Positive	2	0	0	0
Biopsy results	Chronic inflammation	70	11	5	3
	Others	2	1	0	0

Above data analysed preoperative assessment of Kamm's and Wexner's scores. Post-operative comparison of scoring is mentioned in the table below.

b) *Difference between pre and post-operative Kamm score, Wexner's scoring*

Pre KAMM	**Post-operative KAMM score**				p-value
	0	1-2	3-4	>=5	
0	62	3	-	1	
1-2	1	14	1	-	
3-4	1	3	3	-	
>=5	1	-	-	2	0.558

McNemar's test assessing the pre and post KAMM score shows the p-value of 0.558 depicting no significant change in KAMM score after 3 months follow-up.

Pre WEXNER Score	**Postoperative WEXNER Score**				p-value
	0	1-2	3-4	>=5	
0	66	-	1	-	
1-2	4	12	1	-	
3-4	1	-	3	-	
>=5	1	-	-	3	0.199

McNemar's test assessing the pre and post Wexner's score shows the p-value of 0.199 depicting no significant change in Wexner score after 3 -months follow-up.

c) *Factors affecting resting anal tone pre and post draining seton surgery*

Variable	Manometry resting pressure		p-value
	Mean of Resting anal pressure preoperatively mmHg (SD)	**Mean of Resting anal pressure postoperatively mmHg (SD)**	
Gender			
Male	65.28(22.63)	67.85(20.84)	
Female	55.83(13.83)	65.41(19.65)	0.252[a]
Duration of disease			
<1 yr.	62.03(21.57)	68.45(19.72)	
1-5 yrs.	64.65(22.73)	67.42(21.92)	
>5 yrs.	66.03(20.98)	67.78(15.81)	0.716
Diabetes Mellitus			
Absent	65.01(22.33)	67.51(20.88)	
Present	57.67(19.42)	69.14(18.94)	0.167 [a]
Hypertension			
Absent	64.82(22.51)	68.5(20.71)	
Present	63.74(20.62)	63.51(20.99)	0.433[a]
Coronary Artery Disease			
Absent	64.94(22.35)	67.26(20.95)	
Present	53.7(13.68)	75.65(10.83)	NA
History of Perianal surgery in the past			
Never	68.58(22.22)	75.48(17.84)	
Once	67.03(22.92)	66.71(21.61)	
>1 once	55.76(18.98)	59.54(19.64)	0.204
Type of perianal surgery in the past			
Lay open of fistula	66.37(16.67)	64.91(20.96)	
Draining seton	51.93(19.63)	54.12(16.95)	
Incision and Drainage	66.49(23.75)	68.31(22.32)	
Others	70.16(20.84)	77.03(15.96)	0.486
Type of Fistula			
Intersphicteric	47.05(8.56)	55.2(7.07)	
High transsphincteric	66.17(21.97)	69.76(20.82)	
Low transsphincteric	57.98(18.01)	62.96(20.45)	
Supra sphincteric	71.92(29.17)	71.12(22.08)	
Low fistula	89.1(-)	60.2(-)	0.294†
AFB culture/ TB PCR			
Absent	64.73(22.22)	67.62(20.7)	NA

Present	51.85(15.34)	68(25.17)	
Biopsy results			
Chronic inflammation	65.09(22.08)	68.1(20.38)	
Others	45.5(15.26)	53.9(28.67)	NA

NA-p-value could not be obtained due to small numbers in either of the groups of corresponding variables. [a, b] independent sample t –test and One-way ANOVA were used to assess the association of the risk factors by taking the difference of pre and post manometry resting pressure. †compares only group 2, 3 and 4.

Comparison of overall pre and post manometry resting pressure assessed using paired t-test.

Manometry resting pressure		p-value
Mean of Resting anal pressure preoperatively mmHg (SD)	Mean of Resting anal pressure postoperatively mmHg (SD)	
64.45 (22.11)	67.63 (20.64)	0.068

The comparison of squeeze pressure in pre and post operatively

Variable	**Mean of Squeeze anal pressure preoperatively mmHg (SD)**	**Mean of Squeeze anal pressure postoperatively mmHg (SD)**	**p-value**
Gender			
Male	126.34(58.52)	129.08(48.18)	
Female	111.68(47.69)	110.84(24.87)	
Duration of disease			
<1 yr.	117.3(48.62)	124.44(38.56)	
1-5 yrs.	124.55(56.98)	123.72(41.57)	
>5 yrs.	136.7(71.3)	149.25(71.72)	0.228
Diabetes Mellitus			
Absent	125.76(58.29)	128.66(47.98)	0.825[a]

Present	116.25(50.96)	113.29(27.48)	
Hypertension			
Absent	126.79(58.91)	128.08(48.12)	
Present	112.22(47.91)	116.61(29.61)	0.699[a]
Coronary Artery Disease			
Absent	125.05(57.58)	128.31(47.68)	
Present	121.02(60.44)	109.43(9.28)	NA
History of Perianal surgery in the past			
Never	135.86(55.17)	130.24(37.98)	
Once	115.2(54.08)	126.62(39.4)	
>1 once	115.42(64.02)	125.4(64.75)	0.499
Type of perianal surgery in the past			
Lay open of fistula	108.32(46.09)	111.11(22.89)	
Draining seton	110.26(52.61)	122.62(66.98)	
Incision and Drainage	124.22(65.3)	133.36(44.26)	
Others	133.31(55.69)	129.21(38.22)	0.391
Type of Fistula			
Intersphicteric	121.03(86.67)	88.85(16.05)	
High transsphincteric	114.38(47.87)	126.44(42.36)	
Low transsphincteric	120.84(55.4)	128.14(46.28)	
Supra sphincteric	118.07(52.99)	138.59(70.36)	
Low fistula	138.84(63.47)	120(0)	0.380†
AFB culture/ TB PCR			
Absent	125.08(57.81)	127.28(47.25)	
Present	132.94(63.61)	136.1(22.77)	NA
Biopsy results			
Chronic inflammation	126.25(58.04)	127.97(47.07)	
Others	95.47(38.15)	112.9(43.29)	NA

NA-p-value could not be obtained due to small numbers in either of the groups of corresponding variables. [a, b] independent sample t –test and One-way ANOVA were used to assess the association of the risk factors by taking the difference of pre and post manometry squeezing pressure. †compares only group 2, 3 and 4.

Comparison of pre and post manometry squeezing pressure assessed using paired t-test.

Mean of Squeeze anal pressure preoperatively mmHg (SD)	Mean of Squeeze anal pressure postoperatively mmHg (SD)	p- value
117.95 (53.49)	127.48 (46.80)	0.030

There was no significant difference was found between Resting anal pressure and squeeze anal pressure pre and 3 months post operatively following draining seton surgery.

Thus draining seton surgery can be considered as a safe surgery which can be done for the high fistula in ano.

6.Discussion

The draining seton surgery for fistula in ano is a common method of treating high perianal fistula in ano from many generations. Have we really improved from the time of Sushruta's *ksharasootra* is really a matter of debate. Since this is one of the most common problem running from the beginning in human race. Fistula in ano has been a challenge for a surgeons. Many innovative ideas and surgical procedures have been tried in the past, but there has been no fully satisfactory procedure which can be complications free. Current surgical technique also known as draining seton surgery, staged seton surgery has been described in following steps. We used the standard procedure which is used worldwide.

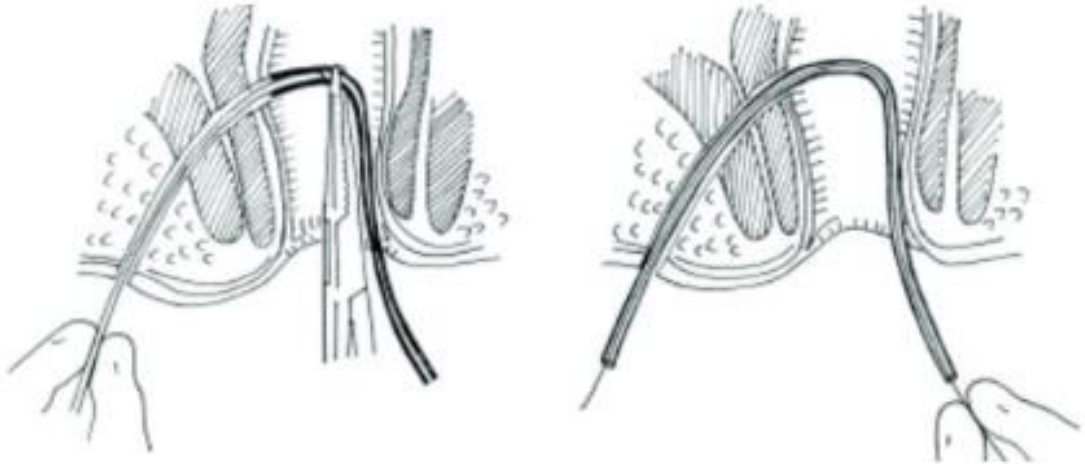
All the patients after explaining procedure underwent surgery on an elective date. After confirming the identity of patient they were anaesthetised with laryngeal mask airway. In few cases intubation was preferred, where it was indicated. But we prefer laryngeal mask airway as the anal tone is not paralysed by this type of anaesthesia. Which is helpful and guides during dividing the muscle fibres near external anal sphincters. We did not administer any antibiotics at induction, as there is enough evidence that prophylactic antibiotics doesn't help in case of dirty surgery.

After patients were anaesthetised they were positioned in lithotomy position with use of normal stirrups or by using Allen's stirrups. Patients' parts were

prepared. Shaving of perianal region was done, scrotum was lifted up to anterior abdominal wall with the help of broad adhesive to enhance the exposure of perineum. Surgeons painted perineum after appropriately scrubbing. Perineum was painted with three coats of skin preparation solution of 7.5% povidone - iodine. After that perineum was draped. The procedure was started with a close inspection of the perineum to look for external opening, to detect any suspicious lesion. Following that digital rectal examination was performed under anaesthesia, to look for the internal opening. Proctoscopy was done under anaesthesia after this and internal openings were identified. In cases when internal opening was not obvious, in such cases hydrogen peroxide was instilled in the external opening to look for internal opening. In cases where we could find an obvious internal opening with a subtle external opening, hydrogen per oxide was instilled in the internal opening of fistula to identify the external opening. Following identification of internal and external opening, a blunt tip probe was gently introduced from external opening of fistula in ano. The care was taken while probing the fistula in ano, not to push it which could have given rise to a false tract.

After passing blunt tip probe through internal and external opening of fistula in ano, the involvement of muscles fibres were assessed. Here we find superiority of laryngeal mask airway over the other methods like endotracheal intubation and spinal anaesthesia. Anal tone remains maintained under laryngeal mask airways and we could assess the thickness of puborectalis muscles fibres involved. We were able to get almost accurate depth of fistulous

tract. It was possible to differentiate between suprasphincteric, intersphincteric, high and low trans-sphincteric fistula. Based of involvement of muscle fibres involvement draining seton surgery was planned. Before proceeding to next step, a careful inspection was done to look for any other subtle fistula in ano / secondary tracts / perianal abscesses. Partial lay opening of fistula was done near external opening of external opening.



Infant feeding tube was threaded over the blunt fistula probe. It was pushed over the probe adequately to avoid the slippage of infant feeding tube. After this infant feeding tube was passed through the fistula tract by pulling the probe outside through the external opening of fistula in ano. After infant feeding tube passes through both internal and external opening, it was pulled outside, and suture tie was done at the perineum with linen tie. Another linen tie was taken 1 – 2 cm distal to the first suture ligature. Extra length of infant feeding tube was cut.

Haemostasis was achieved, another inspection was done for picking up any subtle or secondary fistula in ano. A small paraffin gauze piece was placed on

the raw area externally and simple gauze dressing was done which was fixed with 2 inch surgical micropore surgical tape.

Patients were positioned supine, and covered with a bed sheet. Gradually anaesthesia was weaned off and patients were shifted to trolley. The gauze which was used for covering the wound was removed after 6-8 hrs / during night rounds. None of the patient had significant bleeding in the postoperative period which needed any intervention.

Patients were started on normal diet, most of the patients were discharged on the same evening, rest were sent on the next day morning. They were taught digitation of the partial lay open fistula site with 0.2% lignocaine gel. They were also advised to maintain adequate hygiene of the perianal region. They were followed up in next outpatient clinic and then they went to their home town after getting an elective date for next surgery for seton exit / exchange. They were reassessed reassess prior to their second surgery for assessment continence profile.

This article describes the continence profile of all the patients who presented to Surgery II (colorectal surgery) outpatient clinic between May 2015 and July 2015. These article revolves around 196 fistula in ano patients. 176 patients were males and 20 patients were female. Previous studies have shown male preponderance of 1.8:1 (32). That is magnified in this study probably due to following reasons.

a) This is a referral centre, difficult / tertiary level care cases only come here. Probable there is a low prevalence of complex / high fistula in ano in

female gender. Though this will require a well planned community based study for further assessment.

b) Female patients did not report for medical management of disease
c) Female patients use more of traditional therapy
d) Few female patients did not give consent to participate in this study

The prevalence of gender mismatch in this study is debatable, since this is an institution based study and not a community based study. This cannot represent the actual burden of one community / fistula in ano gender based differentiation. Though these findings can be interpreted as the prevalence of complex fistula in ano is more in male gender. And males seek medical attention for their fistula in ano problem.

Age group in which fistula in ano was mainly presented was between 25 yrs. to 50 yrs. of age group. Almost all patients presented here following consulting a primary health care centre / secondary health centre.

There was no patient who came with a past history of tuberculosis. Among 196 patients 19 patients had history of diabetes mellitus, 32 patients were hypertensives and 10 patients had coronary artery disease. But there was no direct influence of these comorbid illnesses was seen with fistula in ano, incontinence at presentation. Though sometimes it caused a delay in treatment who needed stabilization in their sugars, blood pressures etc. Cardiology clearance was obtained for coronary artery disease patients prior to taking them for surgery.

Among 196 patients 102 patients gave a history of previous surgery in the past, maximum patients (51%) gave history of an incision and drainage in the past. Incision and drainage was mainly done for the perianal abscess. Other patient had some form of surgery for fistula in ano. It means they either had lay opening of fistula, seton placement, and fistula plug/glue application.

On obtaining duration of surgery biggest group had illness between 1 – 5 years duration, almost 63% of all the patient. Only 22% of the patients came within 1 year of their illness started. Rest of the people had their illness for more than 5 years duration. There have been two reasons for this pattern. Generally during early phase of their illness patients took treatment in their local primary / secondary health care centre. They came to tertiary care centre only after the disease persisted following primary treatment / complications occurred. Another reason is there is a sense of careless in seeking medical attention. Most of the patients gave a history of use of topical ointment which was available over the counter. It was mostly advised by a friend / relative / quacks. These ointments were lignocaine gel / GTN ointment / Diltiazem topical ointment / Ayurveda ointments. Thus it generally delays the definitive surgical therapy.

On evaluation these 196 patients their fistula in ano profile revealed that maximum patients have a low fistula in ano, 72 patients had low fistula in ano that means less than third of muscular anal sphincter was involved. These findings were confirmed during surgery while doing examination under anaesthesia. These patients underwent lay open of fistula.

Another group of patient had high number of transsphincteric fistula. 46 patients had low transphincteric fistula in ano, most of these patients had draining seton surgery, but few patients also had lay opening of fistula based on muscular fibres involvement. 59 patients had high transphincteric fistula in ano. Most of these patient who had high transphincteric fistula in ano, underwent draining seton surgery. Few of them had other procedures like fistula plug placement / LIFT etc. 13 patients were diagnosed to have supra sphincteric fistula in ano, who underwent draining seton placement. Among them one patient also had diversion stoma surgery done. Among these patients 6 had intersphincteric extension of fistula tract. These were managed based on the surgeon's preference. Either tract was laid open or a seton was passed through the fistula. Among these 196 patients 104 patients underwent draining seton surgery. 91 patients were followed up after 3 months.

When all the patients were screened with Kamm's score prior to their draining seton surgery, maximum patients were in in a group of Kamm's score of zero. But as the duration of illness prolonged relative risk of development of incontinence increased. It can be due to persistent local inflammation, fibrosis, which replaces muscle fibres with fibrotic tissue. Another reason can be the risk of multiple recurrent abscess and persistent local sepsis which leads to chronic inflammatory changes leading to incontinence.

There was no significant alteration was noticed in Kamm's scoring with respect to comorbid illnesses like diabetes, hypertension and coronary artery disease. There was a relative risk was seen from the number of past perianal

surgeries. More the number of perianal surgeries lead to anal incontinence problem. The type of past surgery did not have any influence on the outcome of the surgery. As it has been shown in this study that most of the perianal surgeries were done for perianal abscess, procedure performed was incision and drainage of abscess.

Among patients who underwent draining seton surgery, Kamm's score assessment was done after 3 months. It revealed following results for 91 patients -

a) Out of 66 patients who had a Kamm's score of zero at the beginning, prior to their first surgery; 3 months later 62 patients had similar results. 3 patients had a Kamm's score of 1 – 2. And 1 patient developed incontinence with a Kamm's score of more than 5.
b) Out of 16 patients who had a Kamm's score of 1 – 2 at the beginning, prior to their first surgery; 3 months later 14 patients had similar results. 1 patient had a Kamm's score of 3 - 4. And 1 patient improvement of incontinence profile with a Kamm's score of zero, probably due to subjective error during the first assessment.
c) Out of 7 patients who had a Kamm's score of 3 - 4 at the beginning, prior to their first surgery; 3 months later 3 patients had similar results. Rest of the patients showed improvement in their continence profile. 3 patient had a Kamm's score of 1 – 2. And 1 patient developed Kamm's score zero.
d) Out of 3 patients who had a Kamm's score of more than 5 at the beginning, prior to their first surgery; 3 months later 2 patients had similar results. One

patient reported significant improvement in symptoms, with a Kamm's score of zero.

Thus this is conclusive that there was no significant change in Kamm's scoring after the draining seton surgery. Draining seton surgery doesn't caused new onset in continence in statistical significant range. This is a significant findings as most of the studies reveal statistical significant incontinence post operatively.

When all the patients were screened with Wexner's score prior to their draining seton surgery, maximum patients were in in a group of Wexner's score of zero. Overall more patients were of male gender as registered in this study so there was male majority here also. As the duration of illness increases relative risk of development of incontinence increases. This was elicited in this study by Wexner's scoring. It can be due to persistent local inflammation, fibrosis, which replaces muscle fibres with fibrotic tissue. Another reason can persistent local sepsis which leads to chronic inflammatory changes leading to incontinence.

There was no significant alteration was noticed in Wexner's scoring with respect to comorbid illnesses like diabetes, hypertension and coronary artery disease, p value was more than 0.6 in all three cases. There was a relative risk was seen from the number of past perianal surgeries. More the number of perianal surgeries lead to anal incontinence problem. The type of past surgery did not have any influence on the outcome of the surgery. As it has been shown in this study that main procedure performed was incision and drainage of abscess.

Among patients who underwent draining seton surgery, Wexner's score assessment was done after 3 months. It revealed following results for 91 patients -

a) Out of 67 patients who had a Wexner's score of zero at the beginning, prior to their first surgery; 3 months later 66 patients had similar results. 1 patient had a Wexner's score of 3 - 4.
b) Out of 17 patients who had a Wexner's score of 1 – 2 at the beginning, prior to their first surgery; 3 months later 12 patients had similar results. 1 patient had a Wexner's score of 3 - 4. And 4 patients improvement of continence profile with a Wexner's score of zero, probably due to subjective error during the first assessment.
c) Out of 4 patients who had a Wexner's score of 3 - 4 at the beginning, prior to their first surgery; 3 months later 3 patients had similar results. 1 patient showed improvement in their continence profile.
d) Out of 4 patients who had a Wexner's score of more than 5 at the beginning, prior to their first surgery; 3 months later 3 patients had similar results. One patient reported significant improvement in symptoms, with a Wexner's score of zero.

Thus this can be concluded that there was no significant change in Wexner's scoring after the draining seton surgery. Draining seton surgery doesn't caused new onset in continence in statistical significant range according to Wexner's scoring system. This is a significant findings as most of the studies reveal statistical significant incontinence post operatively.

On assessing resting on various parameters we found that there was no significant changed based on the gender of the patient. Significant reduction in the resting anal pressure was noticed between the groups which had diabetes mellitus, comparing with a group which did not have diabetes mellitus. Though resting pressure mean in the group with patients with diabetes mellitus was 57.6 mm (Hg), compare to the group which did not have diabetes mellitus their resting pressure mean was 65.01 mm (Hg). But this did not cause a significant drop in continence post operatively. Similar findings were noted in the group where patients were suffering with hypertension.

More than one perianal surgery in the past was also a risk factor reduction in resting anal pressure preoperatively. Post operatively there was no significant drop in anal resting tone. But overall function was on the lower side in this section. As this group had reduced resting anal pressure from the beginning itself. Based on the nature of fistula in ano, intersphincteric fistula had lowest resting pressure to start with 47.05 mm (Hg). Low fistula in ano had least effect on the resting anal pressure with a manometry reading of 89.1 mm (Hg). There was no significant change noticed in the preoperative and post-operative resting anal tone.

The mean of all the pre-operative resting anal pressure was 64.45 mm (Hg), Post-operative mean resting anal pressure tone was 67.63 mm (Hg). Thus since there is no significant change was noticed. It is evident that draining seton surgery does not affects the smooth muscles function which are responsible for resting anal pressure.

On evaluating squeeze anal pressure we found that there was no significant reduction in the resting anal pressure in groups which had diabetes mellitus, comparing with a group which did not have diabetes mellitus. This finding was different from the

resting anal pressure manometry. And there was influence of hypertension also in the squeeze pressure outcome.

More than one perianal surgery in the past was also a risk factor reduction in squeeze anal pressure preoperatively. Post operatively there was no significant drop in anal squeeze pressure tone. But overall function was on the lower side in this section. As this group had reduced squeeze anal pressure from the beginning itself. Based on the nature of fistula in ano, high trans-sphincteric fistula had lowest squeeze pressure to start with a mean of 114.3 mm (Hg). Low fistula in ano had least effect on the resting anal pressure with a manometry reading mean 138.84 mm (Hg). There was no significant change noticed in the preoperative and post-operative squeeze pressure anal tone.

The mean of all the pre-operative squeeze anal pressure was 117.95 mm (Hg), Post-operative mean resting anal pressure tone was 127.48 mm (Hg). Thus since there is no significant change was noticed. It is evident that draining seton surgery does not affects the voluntary muscles function which are responsible for squeeze anal pressure.

Thus it confirms that draining seton surgery doesn't causes significant drop in continence function post operatively. As quoted in some previous studies which showed incontinence level up to 60% post operatively with poor satisfaction with the surgery. (33)

7. Conclusions

Draining seton surgery which is also known as two stage seton surgery or staged seton surgery. Although this procedure was described in earlier articles also, it was reported to have a significant amount of faecal incontinence rate post operatively. Most of the data of previous studies were retrospective and most of the studies included only subjective scoring system. Some studies used nonstandard scoring system as well. Thus we used two most common incontinence scoring system used worldwide, this study is powered by objective assessment of manometry also, and this aspect of an objective assessment was missed in most of the studies. There are not many prospective studies which assessed incontinence assessment after 3 months also.

This study shows that there is significant amount of incontinence present among patients who presented first time in our outpatient clinic with fistula in ano. It was influenced by the duration of disease, the incontinence rate gradually increased with the duration of disease. It was seen significantly high in patients with duration of disease more than 5 years the supraclavicular / high transsphincteric fistulas had a high possibility of incontinence at the presentation. History of previous surgery increases the risk of incontinence at presentation. It increases more with multiple perianal surgeries in the past.

There was no influence of comorbid illnesses like diabetes, hypertension and coronary artery disease on the incontinence profile of fistula in ano.

The objective assessment of anal function revealed results that there was no association of gender on anal resting tone. Duration of disease did not affect the resting anal pressures. There was significant reduction of anal resting pressures were noticed with diabetes mellitus. Though there was no significant influence noted with hypertension and coronary artery disease on resting anal pressure tone. Diabetes probably affects resting anal tone by involving the autonomic nerve fibres.

Previous perianal surgery affected resting anal pressure. It was more for patients who had multiple surgeries in the past. The mean resting anal tone of patients who had multiple surgeries in the past had a mean of 55.76 mm (Hg) of resting pressure. Post operatively it improved to 59.59 mm (Hg). But still this was not as good as patient who did not have any surgery in the past / those who had only one surgery in the past.

Incontinence was seen significantly high in patients with Intersphicteric fistula in ano. Patients in this category had a mean of 47.05 mm (Hg) of resting anal tone. The best continence was seen in patients with low fistula in ano with a mean of 71.9 mm (Hg).

The draining seton surgery did not affect continence profile badly. Average of all the patients who underwent draining seton surgery, had 64.4 mm (Hg) of resting anal tone. Post-operative assessment of resting anal tone gave a mean of 67.63 mm (Hg). Thus it can be concluded safely that there was no significant change of resting anal tome following draining seton surgery.

While assessing squeeze pressure with anal manometry we found that, duration of disease did not affect the squeeze anal pressures. There was significant no significant

reduction of anal squeeze pressures was noticed with diabetes mellitus. Also there was no significant influence noted with hypertension and coronary artery disease on squeeze anal pressure tone. Diabetes probably affects resting anal tone by involving the autonomic nerve fibres which affects tone of smooth muscles fibres called as internal anal sphincter.

Previous perianal surgery affected squeeze anal pressure. It was not more for patients who had multiple surgeries in the past. The mean squeeze anal tone of patients who had multiple surgeries in the past had a mean of 136.7 mm (Hg) of resting pressure. Post operatively it improved to 149.5 mm (Hg). It can be concluded that past history of surgery did not affect squeeze anal continence much. Incontinence was seen significantly high in patients with transphincteric fistula in ano.

The draining seton surgery did not affect continence profile badly. Average of all the patients who underwent draining seton surgery, had 117.95 mm (Hg) of squeeze anal tone. Post-operative assessment of squeeze anal tone gave a mean of 127.48 mm (Hg). Thus we conclude

1- As per Kamm's scoring system 26.2% patients and according to Wexner's scoring system 23.5% patients had some form of incontinence at presentation itself.
2- Draining Seton surgery is a safe surgery, there was no stastically significant short term (3 monthly) complication was noticed like, anal incontinence.
3- Draining Seton surgery can be done for the patient who present with high fistula in anon.

4- There was no additional risks of developing incontinence based on comorbid illness.
5- Intersphincteric fistulas have low resting anal tone, though trans sphincteric fistulas show drop in squeeze anal tone.
6- There was a basal mild incontinence present in patients with fistula in ano. The severity was more in patients who had multiple perianal surgical procedures. Incontinence was also seen in patients with chronic fistula in ano history.
7- The depth of internal opening and involvement of muscles fibres was also a contributing factor for baseline incontinence

Thus it can be concluded safely that there was no significant change of squeeze anal tone following draining seton surgery nor significant change was noted in resting anal tone. Draining seton should be preferred in cases with high fistula in ano in which more than 1/3rd of external anal sphincters are involved.

Limitations and future scope

The development of human race in various fields of life has been quite evident. But satisfactory success rate in the treatment of fistula in ano is still not achieved yet. The post-operative complications which affects anal sphincter muscles restricts the success rate of the surgical intervention.

There was subject based limitations of the study present. All the procedures were done under supervision of a professor / an associate professor / an assistant professors. Procedures were performed by professors /associate professors / an assistant professors / post-graduation residents / interns. Thus there was a wide variety of experience and skill level of operating surgeon which could be contributing factor of the outcome.

Another limitation was all the patients following draining seton surgery, were assessed at the end of 3 months. The actual long term complications were not covered in this study. Probably the outcome of study would have changed if it was a long term follow up study.

Another limitation was that prevalence of the anal incontinence assessed among all the new patients presented in our out patients clinic cannot be the real burden of incontinence of all fistula patients based on following factors.

1 – We included all the patients who presented to our out patients clinic for the first time irrespective of previous surgical interventions. Thus among the group of patients

who had surgical interventions done elsewhere, the current continence profile can be outcome of that surgery.

2 – Some patients who presented first time did not give a consent to be a part of this study.

3 – Since study was performed in a tertiary care centre, most of the patients had some surgical intervention done in the past, either in primary or secondary institution.

The subject based limitation could not be avoided in this study. Since perception of incontinence was variable for various patients, thus we used standard incontinence scoring tools. Anal manometry provides and objective edge over subjective measures, but the squeeze pressure is a voluntary anal pressure generated by patients. It could be not the exact representative of an actual anal tone.

The associated perianal abscess, fissure and other local inflammatory pathology were contributory factors in providing a false high resting pressure tone and low squeeze pressure tone.

Thus another study can be planned with a more number of sample size, a long term follow up. Well planned randomised control trials are the demand of the time. Studies with various modified methods of fistula in ano management like role of stem cells in fistula in ano management.

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Title: Assessment of incontinence among patients with fistula in ano, at presentation and after seton treatment

Serial no. - Date –
Hospital no. -
Name – Male/Female
Age –

1 - Duration of the disease –
2 - Past history of Tuberculosis/Diabetes/Hypertension/Coronary artery disease–

3 - Any previous perianal surgery –
If yes, date and details of surgery –

4 - Number of children (normal/ breech/ Caesarean section /Forceps method) –

History of episiotomy/tear –

5 – Date of surgery –
Type of fistula – Intersphincter/high trans sphincter/low trans sphincter/supra sphincter
Type of surgery – seton/LOF/plug/other
Final biopsy report (biopsy no._____) –

AFB Culture and sensitivity –
TB PCR –

6 – Assessment

	Preoperative	Post-operative
Date of assessment		
Kamm score		
Wexner score		
Manometry – resting pressure		
Manometry – squeeze pressure		

The Wexner Score (Mark as ✔ wherever appropriate)

	Frequency				
Type of incontinence	Never	Rarely	Sometimes	Usually	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears Pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

Never,
Rarely = < 1 in a month,
Sometimes = < 1 in a week, > 1 in a month
Usually = < 1 in a day, > 1 in a week
Always = > 1 in a day

The Kamm Score (Mark as ✔ wherever appropriate)

	Never	Rarely	Sometimes	Weekly	Daily
Incontinence for solid stool	0	1	2	3	4
Incontinence for liquid stool	0	1	2	3	4
Incontinence for gas	0	1	2	3	4
Alteration in life style	0	1	2	3	4

	Yes	No
Need to wear Pad or plug	0	2
Taking constipating medicines	0	2
Lack of ability to defer defecation for 15 minutes	0	4

Never = no episode in the past four weeks
Rarely = one episode in the past four weeks
Sometimes = more than one episode in the past four weeks, but less than one episode a week
Weekly = more than one episode in a week, but less than one daily
Daily = one or more episodes a day

Total Wexner score		
Total Kamm score		

Title: Assessment of incontinence among patients with fistula in ano, at presentation and after seton treatment

You have been diagnosed to have fistula in ano. Fistula in ano is an abnormal connection between anal canal and perianal skin. There is a risk of incontinence associated with fistula in ano. Incontinence is an impaired control over defecation which can lead to involuntary loss of flatus, mucous, liquid or solid stool. Sometimes incontinence is present at the beginning of disease itself, prior to any treatment. However this is often missed. There is also a risk of new onset incontinence following fistula surgery.

Thus you are being requested to participate in this study to check your continence status. For few patients assessment will be repeated after 3 months.

Anal manometry will be used to assess incontinence. Anal manometry is a routine preoperative procedure. It is a safe without any potential risks. It measures pressure of the anal sphincters at rest and on squeeze, sensation of anal canal and neural reflexes which are essential for normal bowel function. A small, flexible tube with a balloon at the tip is inserted into the back passage for this test.

Anal incontinence grading score is a subjective method to assess anal incontinence. You will be asked few questions regarding your bowel habits. It will help us to assess severity of anal incontinence.

Though it will not be beneficial for participants directly, it will be helpful for your incontinence monitoring. It will be beneficial for development of new surgical procedures in future.

You will not be charged any money for participating in this study. You will receive a regular treatment; it will not be changed due to this study. You will also not receive any money to participate in this study. Your participation in this study is entirely voluntary. You have right to refuse to take part in this study or withdraw from this study any time you wish to. If you do so, this will not affect your usual treatment at this hospital in any way.

The results of this study will be published in a medical journal but your identity will not be revealed in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission.

If you have any doubt please ask Dr. Komala Abhishek Reddy, Dr. Rohin Mittal, Dr. Mark Ranjan Jesudasan or Dr. Benjamin Perakath (mobile no: 09843678812/07810046914. Tel: 0416 2282159/ 2282120/ 2282207) or email: karonline@gmail.com

Study Title: : Assessment of incontinence among patients with fistula in ano, at presentation and after seton treatment

Serial No. - **Age -**
Name - **Date –**
Hospital no. -

Please mark in the space provided

(i) I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
[ ]

(iii) I understand that the investigators will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes. [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative: _____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____
Study Investigator's Name: _____

Signature of the Witness: _____

Date:_____/_____/_____

Name of the Witness: _____

Address of the witness -